Prescription drug plan enrollment and patient outcomes in Medicare Part D beneficiaries with diabetes

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ABSTRACT

Kristin Lowe Geonnotti: Prescription drug plan enrollment and patient outcomes in Medicare Part D beneficiaries with diabetes
(Under the direction of Morris Weinberger)

Medicare Part D aims to provide seniors with affordable prescription drug coverage. However, beneficiaries' out-of-pocket costs may vary widely between plans. For Part D to be most effective, beneficiaries should enroll into the prescription drug plan that minimizes total annual out-of-pocket costs. However, several factors, including complex enrollment processes, may result in beneficiaries' failure to enroll into a "lowest-cost plan." This study examines the prevalence and effect of being in a lowest-cost plan on patient outcomes, including: cost-related nonadherence (CRN); clinical outcomes; and health services use among Part D beneficiaries with diabetes.

We identified patients with diabetes who were ≥ 65 years and received primary care from UNC's General Internal Medicine or Family Medicine practices. We combined data from telephone surveys, medical records, and publicly-available CMS cost data. Based on prescribed medications, we calculated: (1) total out-of-pocket medication costs and (2) out-of-pocket medication costs if they were enrolled in a lowest-cost plan. Differential costs are the difference between the total and lowest out-of-pocket costs. These calculations were made twice: once assuming that prescriptions were filled as written, and again with generic substitutions. Descriptive and multivariate regression analyses were used to examine all aims.

75% of beneficiaries are not in lowest-cost plans. Differential costs are substantial: 50% of participants are in a plan that costs them at least $715 ("as written") / $489 ("generic") more than the lowest-cost plan, with a highest difference of over $7,500. On average, participants are paying 30% more than necessary to obtain medications. Additionally, a $1,000 increase in "as written" differential costs is associated with a 36% increase in the odds of experiencing CRN ($p<0.05$). In turn, CRN is associated with poorer outcomes including self-reported health status and increased inpatient stays.

To my knowledge, this is the first prospective cohort study to link patients' plan, CRN and clinical parameters to evaluate Part D. By considering policies that increase the likelihood of

beneficiaries being enrolled in a lowest-cost plan, CMS has the potential to reduce CRN and improve patients' health outcomes.

To Anthony & Will

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LIST OF ABBREVIATIONS

CMS: Centers for Medicare & Medicaid Services

CRN: cost-related nonadherence

FPL: federal poverty level

LIS: low-income subsidy

MA-PD: Medicare Advantage prescription drug plan

MedPAC: Medicare Payment Advisory Commission

PDP: prescription drug plan

PDPF: prescription drug plan finder tool

SNP: special needs plan

CHAPTER 1: SPECIFIC AIMS

Medicare Part D, created under the Medicare Modernization Act of 2003, aims to reduce economic barriers that prevent beneficiaries from filling their prescriptions. Part D provides a federal prescription drug benefit, administered in the private market, for all Medicare beneficiaries. To maximize the effectiveness of Medicare Part D, beneficiaries should enroll into the prescription drug plan that best meets their needs; this can be defined as the plan that maximizes formulary coverage and minimizes annual out-of-pocket costs. Failure to enroll into a lowest-cost plan may leave beneficiaries vulnerable to cost-related nonadherence (CRN), which has been associated with worse clinical outcomes and increased health services utilization. Therefore, the inability to enroll in a lowest-cost plan may ultimately compromise the effectiveness of Part D. This study will examine the prevalence and effect of being in a lowest- cost plan on patient outcomes, including: CRN; clinical outcomes; and health services use among Part D beneficiaries with diabetes.

In this study, patients' medication-related costs is operationalized in three ways: (1) lowest-cost plan enrollment, a dichotomous variable that indicates being in a plan with costs within 10% of the annual out-of-pocket costs in a lowest-cost plan; (2) total out-of-pocket-costs, a continuous variable that indicates the total annual medication expense in beneficiary's current plan; (3) differential costs, a continuous variable calculated by subtracting lowest costs from total out-of-pocket costs.

Four specific aims are examined in this dissertation research:

Primary Aims:

(1) To describe the distributions of beneficiaries being in lowest-cost plans and differential costs; and whether dual eligible status affects the probability of being enrolled in a lowest-cost plan.

Hypothesis:

Dual eligibles will have a lower likelihood of being in lowest-cost plans than non-dual eligibles.

(2) To determine the association between lowest-cost plan enrollment/differential costs and CRN, as well as between CRN and clinical outcomes and health services utilization.

Hypotheses:

2a. Beneficiaries in lowest-cost plans will have a lower likelihood of experiencing CRN than those not in lowest-cost plans.

2b. Beneficiaries with lower differential costs will have a lower likelihood of experiencing CRN than those with higher differential costs.

2c. Beneficiaries who experienced CRN will have worse clinical outcomes related to their diabetes than those who did not experience CRN.

2d. Beneficiaries who experienced CRN will have higher health services utilization than those who did not experience CRN.

Secondary Aims:

(3) To determine the association between total out-of-pocket costs and CRN, as well as between CRN and clinical outcomes and health services utilization.

Hypotheses:

3a. Beneficiaries with lower total out-of-pocket costs will have a lower likelihood of experiencing CRN than those with higher total out-of-pocket costs.

3b. Beneficiaries who experienced CRN will have worse clinical outcomes related to their diabetes than those who did not experience CRN.

3c. Beneficiaries who experienced CRN will have higher health services utilization than those who did not experience CRN.

(4) To determine the association between switching plans and differential costs, plan satisfaction, and CRN.

Hypotheses:

4a. Beneficiaries who switched plans will have lower differential costs (and will have a higher likelihood of being in a lowest-cost plan) than those who did not switch plans.

4b. Beneficiaries who switched plans will have a higher likelihood of being satisfied with their current plan than those who did not switch plans.

4c. Beneficiaries who switched plans will have a lower likelihood of experiencing CRN than those who did not switch plans.

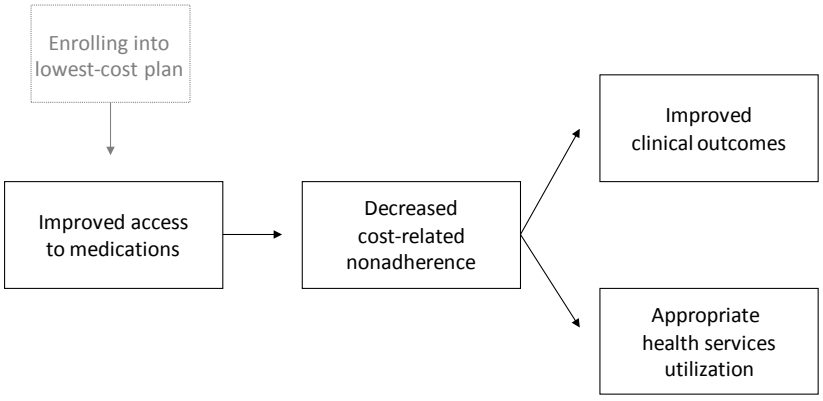
The study sample includes elderly Medicare beneficiaries with diabetes who receive primary care in the General Internal Medicine and Family Medicine practices at UNC. Data are collected from three sources: participant surveys, UNC medical records, and publicly-available CMS plan data. Eligible study participants completed a telephone survey about their Medicare Part D plan, CRN, and plan enrollment decisions. For each beneficiary, I used the CMS Prescription Drug Plan Finder tool to calculate total out-of-pocket costs and lowest costs. I calculated differential costs twice from these two numbers, once assuming that prescriptions were filled as written and again with generic substitutions. For patients who granted access to their medical record, the following data were abstracted: patient characteristics, diagnoses, prescribed medications, clinical outcomes (glycosylated hemoglobin, blood pressure, cholesterol), and health services utilization (inpatient stays and outpatient visits).

CHAPTER 2: INTRODUCTION

Overview

Prior to the enactment of the Medicare Modernization Act (MMA) in 2003, over 25% of Medicare beneficiaries were without drug coverage.[1, 2] With its passage, Part D made prescription drug insurance available to all Medicare beneficiaries. This legislation, considered the largest expansion of Medicare since its inception,[3] aims to improve access to, and affordability of, medications. Beginning in 2006, it is administered in the private market through stand-alone and Medicare Advantage prescription drug plans. For Part D to achieve its intended benefit, beneficiaries should enroll and remain in a plan that minimizes their annual out-of-pocket expense to obtain all prescribed medications. In so doing, individuals may be more likely to obtain their medications, thereby decreasing their cost-related non-adherence (CRN) and, in turn, improve clinical outcomes and decrease inappropriate health services use (Figure 1).[4-6]

Figure 1: Proposed relationships under Part D



Types of plans

Private prescription drug plans (PDP) that offer Part D coverage contract with the Department of Health and Human Services to administer the Medicare Part D drug benefit. Drug benefits are offered in 34 geographic regions of the United States through stand-alone PDPs, Medicare Advantage

plans (MA-PDs), and Special Needs plans (SNPs). As compared to stand-alone PDPs, which only cover prescriptions and are meant to supplement those in traditional Medicare, MA-PDs offer both medical care and drug benefits under one plan (formerly called Medicare + Choice). SNPs are a type of MA-PD that target vulnerable subgroups, including the institutionalized, dual-eligibles, and beneficiaries with particular chronic conditions. SNPs aim to improve care for these groups through improved care coordination.[7] While PDPs are offered at the state-level, MA-PD and SNP offerings vary by county. The Center for Medicare and Medicaid Services (CMS) gives rebates to MA-PDs to encourage Medicare enrollees to move into managed care plans. MA-PDs are more likely to offer enhanced benefits such as vision coverage or fitness memberships. This may be due to rebates that are offered by CMS, which are intended to either supplement the benefits package or to offer lower premiums.[8] However, these plans generally also have more limited provider networks.

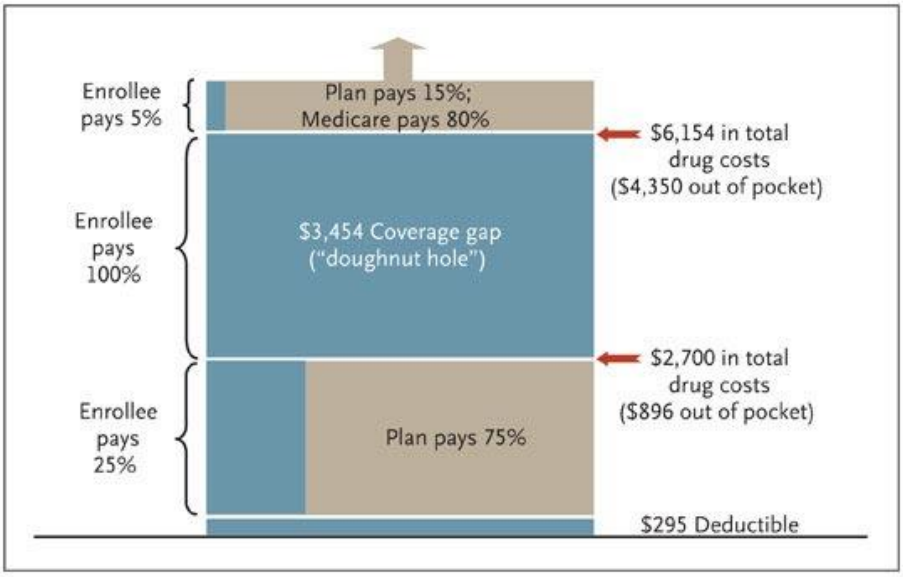
There are many sponsor organizations (insurance companies) from which individuals can choose or be assigned. Each sponsor organization can have up three plans in a given region. Nationally, there are 1,576 PDP options. In North Carolina in 2009, there were 49 PDPs offered by 21 sponsor organizations. There are approximately the same number of MA-PD options, as well as approximately 10 additional SNP options, in each NC county. There are about 7% fewer PDP and 10% fewer MA-PD offerings in 2010 as compared to 2009.[9] Despite the large number of options, the market is fairly consolidated. In 2009, the top five insurance companies (UnitedHealth Group, Humana, Universal American Corp., Coventry Health Care, and Wellpoint) accounted for 55% of Part D enrollees.[10]

Standard benefit

CMS determines a standard benefit each year (Figure 2), but each sponsor organization can choose to offer a different plan as long as its coverage is at least actuarially equivalent. Only 10% of PDPs offered the standard benefit in 2009, down from 12% in 2008.[10, 11] In 2009, the standard benefit started with a $295 deductible. After meeting the deductible, enrollees pay 25% cost-sharing for all drugs, with 75% paid by the plan until covered drug spending reaches $2,700. At that time, the enrollee hits the coverage gap, commonly referred to as the "doughnut hole." While in the doughnut hole (spending between $2,700 and $4,350), the enrollee is responsible for 100% of drug costs. After reaching the $6,154 catastrophic threshold (spending $4,350 out-of-pocket), there is 5% cost-sharing on the part of the beneficiary, with the plan paying 15% and Medicare paying 80% (or $2.40 for generics; $6.00 for brands, whichever is higher). The $4,350 must be comprised of "true out-of-

pocket spending," in which off-formulary medications and cost-sharing by some sources of supplemental coverage (i.e. employer-sponsored policies) do not count.

Figure 2: Standard benefit (2009) [12]



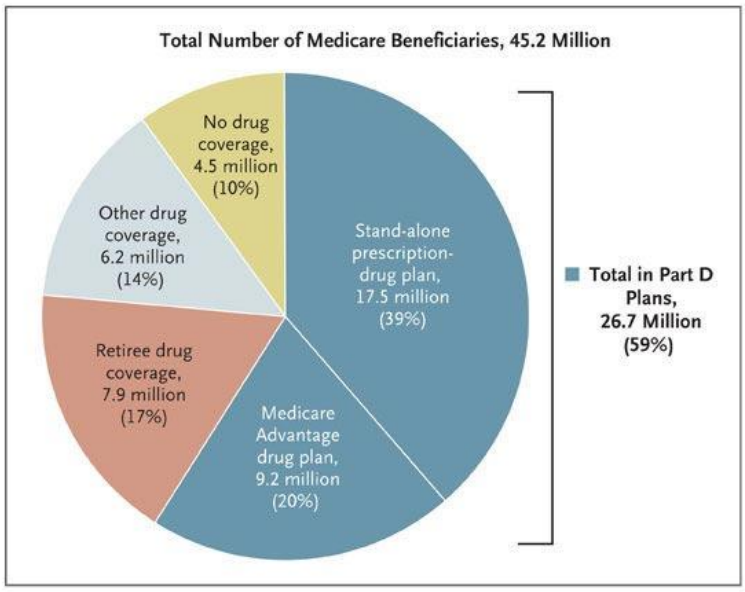
All sponsor organizations must offer at least one standard benefit plan as described above. They can then offer up to two additional plans with enhanced benefits. These enhanced generally offer more comprehensive coverage, with the extra costs often being passed on to the beneficiary. Because the majority of sponsor organizations carry multiple plans, most offer at least one with enhanced benefits. For example, in NC in 2009 Humana offered: Humana Standard; Humana Enhanced; and Humana Complete. Humana Complete has a premium over three times higher than the other two, but is the only one of the three plans to offer coverage during the gap. The majority of PDP enrollees in 2007 (61%) enrolled into a standard benefit plan.[8]

There has been an increase in plans that offer gap coverage for both PDPs (15% in 2006 and 29% in 2008) and MA-PDs (28% in 2006 to 51% in 2008), although the type of coverage has changed. In 2008 no PDPs (and only 1% of MA-PDs) offered gap coverage of both generic and brand-name drugs.[13] This can have cost implications for beneficiaries who rely on brand-name drugs and also have a gap in their coverage.[13] Approximately 3.4 million beneficiaries (~13%) were anticipated to hit the coverage gap in 2007, most of whom would not get out of the doughnut hole before the end of the year.[10]

Enrollment

Over 90% of all Medicare beneficiaries have obtained some form of prescription drug insurance: 26.7 million people are enrolled in Part D plans, while 14.1 million have an alternative other form of drug coverage.[10] While MA-PDs are increasingly present, the majority of Part D beneficiaries are enrolled into PDPs: of the 26.7 million in Part D plans, about 66% are in PDPs and 34% are in MA-PDs.[10]

Figure 3: Part D enrollment (2009)[12]



Adverse selection

Differences have been observed as to the types of beneficiaries who are enrolled in PDPs versus MA-PDs. PDP enrollees tended to be older, poorer, sicker, and more rural than their MA-PD counterparts.[14] In addition, early enrollees have higher utilization and out-of-pocket costs than those who enrolled into the benefit later and than those who chose not to enroll.[15] Those with lower self-reported health status also indicated significantly less intent to enroll.[16] These enrollment patterns are somewhat expected and may reflect adverse selection because: (1) all duals, a group that is generally poorer and sicker, were auto-assigned to PDPs only (rather than to MA-PDs as well) and (2) MA-PDs aggressively market to healthier seniors. Moreover, similar adverse selection has been seen in elderly

non-Part D populations, where one study showed that having drug coverage is associated with a $308 increase in drug expenditures.[17] CMS tries to combat adverse selection in enrollment by enforcing a financial penalty on late enrollment. Those who are eligible but not enrolled will face a penalty equal to 1% of the national average premium for each uncovered month that they were eligible for Part D, but had no alternative creditable coverage. This penalty will be assessed each month, in addition to monthly premiums, beginning at the time that the beneficiary receives Part D benefits.

Low-income subsidy

CMS offers a LIS (also referred to as "extra help") to beneficiaries who are below 150% of the Federal Poverty Level (FPL). This includes dual eligibles, individuals enrolled into the Medicare Savings Program (MSP), or individuals who receive Supplemental Security Income (SSI), as well as individuals not in these programs but who have annual incomes below 150% FPL ($12,150) and with assets less than $12,510 (2009).[10] The criteria for being dually eligible vary by state. There are approximately 7.4 million dually-eligible Medicare beneficiaries nationally.[18] The level of subsidy depends upon income, with full-duals paying $1.10-$2.40 for generics and $3.20-$6.00 for brand-name drugs in 2009. Others pay more based upon a sliding scale, with a maximum of 15% co-insurance. Plans that enroll LIS-individuals tend to have tighter formulary control as a means of controlling costs among a population that tends to use more medications. They cover an average of 83% of drugs, as compared to 90% of drugs for non-qualifying plans.[9] There is no coverage gap for all on-formulary medications except for the highest subsidy level. However, any off-formulary drugs cost full retail price. Dual eligibles automatically receive extra help; however, others must apply for the LIS benefit in order to receive it.

Part D spending

Costs to CMS

CMS makes prospective payments to plans on behalf of beneficiaries; in contrast, reinsurance and LIS cost-sharing payments are retrospective. The prospective payments include a direct subsidy, in which plans are paid a monthly payment equal to a share of the national risk-adjusted average bid. The subsidy from CMS to plans averages 74.5% of basic coverage.[8] In addition, there is a reinsurance mechanism whereby 80% of drug spending above the catastrophic limit is paid by CMS. Risk corridors, which have widened each year, also limit sponsor organizations' losses or profits.[8]

In 2005, the Congressional Budget Office estimated that Medicare Part D would cost $558 billion between its implementation and 2013.[19] According to CMS data, $47 billion was spent on Part D benefits and premiums in 2006. Of this, $44 billion was spent by Medicare, with the remaining $3 billion spent out-of-pocket by beneficiaries.[8, 20] In 2009, this spending increased to $53.4 billion.[9] These costs have been less than originally anticipated; however, the financial investment into Part D has been substantial.[8]

Formulary

CMS sets guidelines that all Part D plans must follow, including which drugs may be covered on plan formularies. For instance:

- No over-the-counter drugs can be on a formulary;
- Anything that Part B covers cannot be covered by Part D;
- All drugs in six therapeutic classes must be covered; and
- Generally, at least two drugs per therapeutic class must be covered unless only one is available.[9]

Beyond these guidelines, insurance companies may design their formularies as they wish, which leads to substantial variation in formulary design. This formulary variation, rather than premium variation, is what mainly drives the wide range in out-of-pocket expense. Insurance companies use formulary design to balance access to medications with controlling growth in total spending.[9] Most beneficiaries (80%) are in 3-tiered plans in which the first tier contains generics; the second tier contains preferred brand-name; and the third tier contains non-preferred brand-name drugs. An increasing number of formularies includes a separate specialty tier, on which biologics and other particularly expensive agents are placed. The 3-tier system effectively controls medication use and the associated costs.[21-24] However, cost-sharing amounts and covered drugs can vary widely between plans: the number of drugs listed on-formulary varies between 37-100% of drugs reported to CMS.[9]

Insurers also use coverage exemptions appeals and utilization management tools (prior authorization, quantity limits, step therapy requirements) to control access to certain medications. In practice, the use of such tools is infrequent: prior authorization was used on 8% of drugs; step therapy used for 1% of drugs; and quantity limits for 12%.[8] In addition, medications that are not covered can still be obtained as if they were on formulary by going through an exemptions paperwork process,

which involves the physician. In practice, however, very few beneficiaries use the exemptions process, and over half of beneficiaries are not even aware of this option.[25]

Medication use by, and costs to, beneficiaries

Prior to the implementation of Part D, Pauly (2004) projected the impact of the policy on medication use and spending.[26] In theory, Medicare coverage affects medication use via out-of-pocket costs to the beneficiary. Those without drug coverage would significantly increase use, but those already having drug coverage (~75% of the population) would not significantly alter their prescription drug spending. Some of the increase would result from overuse due to moral hazard, rather than in improvement in underuse due to new insurance coverage. Therefore, according to this study, Part D would reduce overall user cost by 14% and increase medication use by 6%.[26]

Empirically-based studies have found that Part D increases average medication use by 6-13%, while decreasing average out-of-pocket costs by 13-18%; the absolute dollar savings are small and depend upon previous coverage and time of enrollment.[15, 27-30] In a pre-post-2006 study, Lichtenberg and Sun (2007) compared retail pharmacy claims data for elderly (>65) and non-elderly to compare Medicare enrollees and non-enrollees. They found that drug utilization, operationalized as mean number of days of therapy, increased by 12.7%, while the mean amount paid decreased by 18.4%. This accounts for an overall decrease of 6% in amount paid by beneficiaries, which is similar to the above theoretical estimate. In contrast, third parties experience a 22.3% increase in amount paid.[27] Similarly, Yin, et al. (2008) estimate that after Part D enrollment was stable (from May 2006 forward), medication utilization increased by 5.9%, but out-of-pocket costs decreased by 13.1% ($5.20).[15] It was not possible to link this drug utilization to health outcomes because the study was based on pharmacy claims data. A recent study by Zhang, et al. (2009) found that among Medicare Advantage enrollees, Part D reduced out-of-pocket spending by 13.4% for those without prior coverage, and by 15.9% for those with prior coverage that had a cap.[30] Results from this study also show that the actual dollar amounts attached to these percentages are small (<$50).[31] However, this estimate is only indicative of savings from enrolling into *any* Part D plan, rather than into a *lowest-cost* plan. Therefore the savings may be even greater if the enrollee is in a lowest-cost plan.

Cost sharing varies by beneficiary characteristics. Medication spending by beneficiaries who previously lacked insurance for medications increased 74% after Part D implementation. The increases were less for those with previous coverage.[31] Sicker beneficiaries have higher medication expenditures than healthier beneficiaries.[15, 32] For those with diabetes and no previous coverage, there was a 44% increase in the number of prescriptions filled for diabetic and lipid-lowering mediations.[31]

As expected, cost-savings were greatest for poor beneficiaries, as out-of-pocket spending declined most significantly for duals and LIS-eligibles, but less so for the general Part D population.[29] Other analyses suggest that duals were not adversely impacted for drug utilization or out-of-pocket expense when making the transition from Medicaid to Part D: their drug utilization remained constant and they did not have different out-of-pocket expense relative to a control group.[33, 34]

Enrollees pay highly variable prices across plans. PDP copays can range from $0 to $25 for generics; $15 to $59 for preferred brand name drugs; and $35 to $93 for non-preferred brand name drugs.[8] 26% of all Part D beneficiaries spent more than $100/month on prescriptions, and 8% spent over $300/month (significantly less for duals).[14, 35] On average, cost-sharing for all beneficiaries has increased over time, in part because premiums were comparatively low in 2006 in order to attract enrollees.[36] While many plans increased premiums, plans with the largest proportion of market share disproportionately increased their premiums relative to other plans in the market.[8] From 2007-2008, the average premium for the top three plans rose 27%.[36] Humana's average premium was $9.51 (2006); $15.14 (2007); and $25.82 (2008). UnitedHealth's basic plan premium was $25.18 (2006); $29.57 (2007); and $40.36 (2008).[36] This represents approximately a 170% increase for Humana and 60% increase for UnitedHealth between 2006 and 2008. It appears that cost-sharing will continue to rise in the future. This could drastically affect an individual beneficiary's out-of-pocket expense, particularly if they were unaware of the increase and did not re-evaluate or switch plans accordingly. Increased cost-sharing, without the continued potential for cost-savings due to initial enrollment, can cause beneficiaries to face prohibitive cost barriers that may prevent them from obtaining medications. If this occurs, Part D may not achieve its intended benefit of improving access to and affordability of medications for a population who relies on them to maintain their health.

Part D implementation

Law Architecture

When the MMA was proposed, the implementation of Part D through the private market was heavily debated. Such privatization of a public benefit was unprecedented.[37, 38] The architecture of the benefit relied heavily on the basic assumption that competition among multiple private plans would increase efficiency and keep costs down.[8, 29] The combination of competition and "consumer self-interest" were intended to make the market "largely self-regulating, with minimal supervision by the Center for Medicare and Medicaid Services and its Office of the Inspector General."[39] The resulting political compromise dictated that the drug benefit was provided by private companies, but

government would intervene if there were not at least two Part D offerings in a given region.[3] At the time of the legislative debate, it was unclear whether insurance companies would be willing to enter the market voluntarily.[12] However, it was important that multiple plans participated in order to produce the necessary competition in the private market. Therefore, CMS created incentives, including risk corridors and reinsurance, to ensure market participation. As a result of the circumstances, a multitude of plans entered the market. The fact that there exists a multitude of plan choices is central to the way in which Part D has affected beneficiaries.

Choosing a Part D plan

Under traditional health insurance, the purchaser's degree of risk aversion influences their decision to purchase insurance: more risk averse individuals will be more likely to purchase insurance. However, purchasing medication insurance in the Part D market may function differently than in the traditional health insurance market because the individuals' risk or expected value of loss is largely unknown. That is, past medication utilization is generally a good predictor of future medication utilization in a chronically-ill elderly population, such that purchasers of medication insurance, such as Medicare Part D, may enter the market with a greater degree of certainty.

Even so, Part D plans can vary with respect to their benefit structure. While they must be at least as generous as CMS' standard benefit, some plans may waive deductibles while others will not. Two actuarially equivalent plans may be structured such that one offers lower premiums, but relatively higher copays, while the other has higher premiums and lower copays. These cost structures could be a factor when a beneficiary is deciding between plans. Therefore, two "lowest-cost plans" may differ in their benefit structure such that their total out-of-pocket costs are similar, but their marginal parts (deductible, premium, and copays) differ.

CMS' implementation strategies for enrollment

Given this vast array of choices, CMS implemented two strategies to help beneficiaries enroll in plans. First, all non-dual beneficiaries who desired coverage were required to choose among plan options, with assistance tools including an online plan finder tool and a telephone hotline. Second, all dual eligibles were randomly auto-assigned to qualifying PDPs at the start of the benefit.

Enrollment assistance for non-duals

The first enrollment assistance strategy targets the general Medicare population. CMS created two tools to help beneficiaries choose between plans. First, they developed a "Prescription Drug Plan Finder" (PDPF) tool on Medicare's website. This tool, made available in October 2005, was designed to help beneficiaries and advocates compare multiple plan options and choose a Part D plan. By entering all of one's drugs, the output will give information such as drug coverage, estimated annual out-of-pocket expense, and pharmacy preferences.[40] However this tool is greatly underutilized. Just before benefit implementation in January 2006, only 6% of seniors had visited the Medicare.gov website.[41] Additionally, 76% of seniors reported that they had never been online.[41] Even for the small number of seniors who could use the Medicare website, 72% of them were unable to successfully select a drug plan or had other usage problems that prevented them from selecting a plan.[42] Therefore, despite its abundant information, the PDPF may not be very effective in helping seniors pick plans.

Second, for beneficiaries who are unable to access this tool online, CMS operates a 1-800-MEDICARE toll-free phone number. In 2006, only 15% of beneficiaries have called the number, which was up from 8% in 2005.[41, 43] In focus groups, beneficiaries report that calling 1-800-MEDICARE was frustrating and they remained confused even after the phone call.[25, 44] In addition, beneficiaries are advised to visit their local State Health Insurance Assistance Program (SHIP). However, awareness of these programs, and others that provide assistance, is low among beneficiaries.[25]

Random auto-assignment for dual eligibles

Aiming for a smooth transition from Medicaid to Medicare Part D, full duals were randomly auto-enrolled into PDPs unless they chose a particular plan on their own, with coverage to begin January 1, 2006. Partial duals experienced facilitated enrollment, in which they were given more time to choose a plan on their own. Because auto-enrollment and facilitated enrollment are essentially the same mechanism, just occurring at two different time points, we refer to them as random auto-assignment.[45] If more than one PDP had a premium at or below the LIS amount, the beneficiary was randomly assigned among the qualifying plans. All LIS-beneficiaries, even those not auto-enrolled, must choose a benchmark plan or they must pay the difference in cost. Notably, all LIS-beneficiaries are able to change plans once per month (as compared to others who can only change plans annually during the open enrollment). However, while duals are allowed to switch plans monthly, only 11% of duals switched plans during 2006.[14]

The rationale for auto-assignment was multi-faceted. First, there was concern about the transition from Medicaid to Medicare Part D medication coverage, and auto-assignment ensured that all duals were covered by the start of the benefit. Second, auto-assignment allowed plans to save on marketing.[8] Third, equal numbers of duals were assigned to each participating PDP, which distributed the beneficiaries equally across plans. Fourth, CMS induced competition by setting the benchmark premium, because multiple plans compete to gain access to the LIS-population, whose drug costs are mostly subsidized by CMS.[8] Plans compete to set their bid to CMS at or below the benchmark premium if they wish to enroll LIS-eligible individuals. In 2006 in NC, there were 14 benchmark LIS plans. In 2008 in NC, 17 of the 51 PDPs were at or below the benchmark premium. In 2009 this decreased 11 LIS plans. Each year, some plans may re-set their premium and may not meet the benchmark, in which case they can no longer enroll LIS-beneficiaries. From 2007 to 2008, 62% of benchmark plans (nationally) retained their status to enroll LIS individuals.[8]

Each year, a portion of LIS beneficiaries whose plans lose qualifying status must be re-assigned to a new qualifying plan. From 2006 to 2007, CMS re-assigned 1.1 million beneficiaries. From 2007 to 2008, they re-assigned 2.6 million beneficiaries (22% of all LIS).[8] From 2009 to 2010, almost 3 million LIS individuals were affected. 1.06 million had to be reassigned because their plans lost benchmark status.[9] Choosers (the LIS beneficiaries who chose a plan on their own or switched out of the initial auto-assignment) are not reassigned if their plan loses benchmark status. Instead, they must switch plans on their own or pay the difference to stay in their current plan. 1.7 million choosers were in plans at the end of 2009 that didn't qualify for 2010. However, they are not automatically re-assigned, so they either had to know to choose another plan, or are paying the difference in costs.[9]

Both the enrollment assistance tools and the auto-assignment of duals were intended to facilitate beneficiaries getting into plans that met their needs, which is also ideally a lowest-cost plan. However, it is not clear that these strategies were effective in helping beneficiaries navigate into lowest-cost plans.

Consequences of CMS implementation strategies

Part D has largely achieved its goal of increasing access to medications. Before Part D, over 25% of beneficiaries were without drug coverage.[1, 2] As of February 2009, over 90% of all beneficiaries had obtained some form of coverage: 26.7 million people are enrolled in Part D plans, while 14.1 million have an alternative other form of drug coverage.[10] In addition, Part D has increased drug use and reduced beneficiary costs.[15, 27, 28] Those without previous drug coverage benefited the

most in terms of increased access to medications with an associated decrease in out-of-pocket expense. Despite this success, the multitude of plan options and auto-assignment of duals may have led to negative consequences; in particular, enrollees often do not enroll into a lowest-cost plan. In addition to the random auto-enrollment of duals without consideration of costs or coverage (described above), several other factors may contribute to this issue, including: (1) lack of knowledge; (2) practitioners unable to offer adequate assistance; (3) most beneficiaries don't switch plans; (4) formulary coverage for auto-enrollees; and (5) overwhelming number of choices.

(1) Lack of knowledge

Polinski, et al. (2010) conduct a systematic literature review examining Part D beneficiaries' knowledge of the benefit, and how this impacts enrollment decisions and plan choice. They found that beneficiaries had considerable confusion surrounding the benefit. A substantial proportion of beneficiaries lacked knowledge with regard to the benefit in general, the low-income subsidy, and elements of benefit design (most frequently the coverage gap).[46] Nonwhites, those with lower SES, poorer health, and lower cognitive ability had significantly less knowledge of the benefit.[39] Even after enrolling into a plan, beneficiaries may remain confused about details such as payment caps and coverage gaps. One study of a MA-PD population reported that only 40% of beneficiaries were aware that their plan had a coverage gap and its cost-sharing implications.[47]

Another study found that 68% of elderly health plan members either did not know that they had a payment cap or did not know their cap level if they had one. Although almost all participants knew when they exceeded the cap (because their copayments greatly increase), the majority did not know beforehand that they were about to hit the cap.[48] This lack of knowledge may prevent beneficiaries, particularly those who are more vulnerable, from enrolling into a plan that best meets their needs. This may be problematic for beneficiaries because they may face unexpected costs throughout the year that could pose cost-related barriers. The individuals who were unaware more often reported having a financial burden.[47] In general, knowledge of drug benefits is limited and gets more limited with increasingly complicated benefit designs.[49] This is particularly problematic in the context of Part D, where over 3 million beneficiaries hit the coverage gap among an elderly population that must rely on drug therapies.

Beneficiaries may also lack appropriate knowledge on how to use their current medication list to enroll into a lowest-cost plan. While prescription drug expenses are persistent among the elderly, the actual drugs that are prescribed can vary from time to time. Domino et al. (2008) examined this in the context of Medicare Part D to determine whether selecting a plan at the beginning of the year may

attract an uncertainty loss (financial loss) by the end of the year if medication changes are made during the year. 43% of beneficiaries change prescriptions during a given year to the extent that another plan would have made more financial sense, with an average loss of $556. Total out-of-pocket expense due to these changes can drive costs such that beneficiaries would have saved money by switching plans.[50]

(2) Practitioners unable to offer adequate assistance

Between 70-80% of seniors agree that the Medicare drug benefit is too complicated[51, 52] and many lacked basic knowledge and understanding about how the benefit was administered.[41] Although patients trust doctors and pharmacists to provide drug information,[53] these professionals lack the time and/or knowledge to provide adequate Part D enrollment assistance.[25, 41, 51]

(3) Most beneficiaries don't switch plans

Beneficiaries who fail to enroll in a lowest-cost-plan have the opportunity to select a better plan at re-enrollment. However, despite a significant proportion of beneficiaries not being enrolled in lowest-cost plans, only 6-8% switched plans.[14, 54] Even among LIS-beneficiaries, who are allowed to switch their plan each month, only 11% switch in a given year.[14] Preliminary evidence shows that beneficiaries are not re-evaluating plan options each year, which can leave them in plans that are not lowest-cost.[55, 56] One study found that 90% of participants could have saved money by switching plans during open enrollment. However, less than half of participants who were eligible to switch plans (and therefore save money) chose to do so.[56] This could have been due to the relatively small median savings ($98), but it is also possible that other barriers exist, including: lack of knowledge of other options; avoiding the tedious switching process; being afraid that switching would cause worse problems; and requiring, but not receiving, assistance to switch.[25, 46, 57]

It is likely that beneficiaries don't switch plans due to the confusion surrounding the complex enrollment process[25] and may be paralyzed by the overwhelming number of options. An overwhelming majority of beneficiaries that are surveyed about their intentions to switch plans report that they intend to keep their current plan.[46] Many beneficiaries may be afraid that even if their current plan is not perfect, there is no guarantee that a new plan would be any better. In focus groups, participants state that they are overwhelmed by the complexity of choosing a new plan, and it was so difficult to select a plan at the start of Part D that they did not want to "rock the boat" and try to select a new plan, even if they were aware that the costs in their current plan had risen.[25] Thus, despite the

financial consequences of not switching plans, many Part D beneficiaries choose to stay in their plan, suggesting other barriers to switching.

(4) Formulary coverage for auto-enrollees

Duals who were randomly assigned to plans did not have the opportunity to select a plan based upon formulary coverage or other benefit design features. Therefore, out-of-pocket expense stemming from off-formulary medications may be particularly problematic for these beneficiaries. To estimate the frequency with which dually eligible patients are covered by a lowest cost plan, I conducted a pilot study. I found that 9 out of 17 plans were lowest-cost for a given medication list, while the others ranged from 220% to 700% higher costs. This cost variation is mainly driven by medications that are off-formulary. For all on-formulary medications, the copays for duals are standardized to minimal copays (ranging from $1.10-$6.00 in 2009), in which case not only are the costs not highly-subsidized by CMS, but they are not covered at all (so the dual eligible will have to pay 100% out-of-pocket to obtain the medication.)

(5) Overwhelming number of choices

Choice is a fundamental tenant upon which Part D is built: there are a multitude of plan choices in the private market, and it is the individual beneficiary's responsibility to decide which best suits their needs. Plan selection directly influences out-of-pocket expense, such that choosing or being placed into a plan that does not minimize costs may have detrimental impacts for a beneficiary. Little is currently known about how beneficiaries make choices in Part D.[58] For Part D to function according to the economic principles upon which it is based, the following scenario must occur:[39]

> "In evaluating Part D alternatives, consumers need to take into account not only their current pharmacy bills, but also the probabilities of developing new health conditions that will require treatment, and the distribution of costs of these treatments. They need to understand the formularies, approval rules, and copayment tiers of alternative plans, and how these may change over time. As a result, consumers are being asked to make relatively complex plan assessments, generally with incomplete information on future prospects."

Rational choice theory posits that individuals will make choices based upon maximizing their utility—maximizing benefit and minimizing cost. Therefore, more choices are better because it creates a higher likelihood that a utility-maximizing choice is available for the individual.[52] This

theory rests on the assumptions that: (1) there is sufficient information available to make the choice; (2) the individual is able to decide between the choice alternatives; and (3) the individual won't regret the choices not picked.[52]

Certainly, offering multiple choices has the potential for making decisions that maximize utlility for an individual. However, recent research has begun to challenge whether more choices are always better. The notion of "bounded rationality" suggests that cognitive limitations may preclude individuals from being able to successfully choose among a multitude of choices. With limited memory, time, and knowledge, individuals may not be choosing an option that actually maximizes their utility.[52, 59] Emerging research in decision sciences, psychology, and behavioral economics suggest that being presented with too many choices can be problematic, and can cause individuals to make decisions that do not maximize their utility.[60-62] This may particularly be the case for elderly individuals, who are likely to have more: (1) chronic conditions; (2) prescribed medications; (3) cognitive limitations; and (4) complex decision-making processes.[62] In these instances, elderly decision-makers with more information available to them are less likely to use that information effectively.[60] In addition, individuals may be less likely to participate in markets where they have more choice.[37] One recent working paper, based on laboratory experiments and field data, suggests that a larger set of choices is associated with a stronger preference for simple options that are more easily understood. This supports the idea that "even though the *best* option becomes better as the choice set becomes larger, the *average* option becomes worse." Given this, the person making the decision may have a preference to select a simple option when there is a large choice set.[63] Amid the confusion, beneficiaries choose plans based upon brand loyalty, information from a plan's agent, or other non-systematic approaches, rather than objective criteria regarding cost and/or formulary coverage.[44, 46]

Evidence suggests that elderly beneficiaries are overwhelmed by plan choices and are not making efficient choices, which is "inconsistent with optimization under full information."[37] Thus, although seniors are expected to choose the plan that best meets their needs (i.e. maximizes their utility), they have limited ability to utilize full information, and may be overwhelmed by the multitude of plan choices. This "choice overload" may prevent many beneficiaries from enrolling into the most rational (generally considered the lowest-cost) plan. Hanoch, et al. (2009) examined the issue of "rational" choice in selecting a Medicare Part D plan by conducting an experiment in which 192 adults (ages 18+) were randomly assigned to a choice set of 3, 10, or 20 plans. Using factual questions, they found that just over half of participants (56%) were able to identify the plan in their set that minimized total annual cost. After controlling for appropriate covariates, age did not

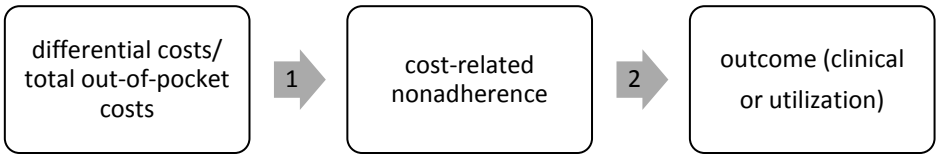
significantly predict the likelihood of successfully identifying a low-cost plan.[58] In a study in which participants were given a set of hypothetical plan options, only 36.3% of those who intended to enroll picked a plan that minimized expected present value of annual out-of-pocket costs.[39] However, participants were only presented with 5 options intended to represent key plan features, far fewer than the 50-some choices offered to many Part D beneficiaries. It is particularly troublesome that many beneficiaries are confused about their plan's cost-sharing and their own out-of-pocket costs. In one mailed survey, beneficiaries state that copayment amounts were the most important factor influencing plan choice.[44, 46] However, a minority of beneficiaries actually compare costs between plans.[44, 46, 64] This could lead to paying more than necessary to obtain necessary medications (differential costs).

In summary, although Part D was designed to increase access to, and affordability of, medications, its complex enrollment process may limit its overall effectiveness. Beneficiaries must choose or are randomly-assigned among multiple plan options. Due to variations in formulary and benefit design, annual out-of-pocket costs can vary widely between plans. Given the complexities and confusion outlined above, it is likely that many are not in plans that minimize their out-of-pocket expense. Since Part D aims to improve health outcomes by increasing medication access, suboptimal plan choice due to enrollment complexities may lead to CRN, which can in turn lead to worse clinical outcomes and increased health services utilization.

Potential consequences of not being in a lowest-cost plan

Prohibitive cost-sharing has been shown to be associated with higher CRN, increased inappropriate health services utilization, and worse health outcomes, as detailed below. These relationships will be investigated in this research (Figure 4).

Figure 4: Pathway to be estimated in dissertation study



Cost-related nonadherence

CRN includes skipping doses, stretching between refills (i.e. splitting pills, taking less than prescribed) or not filling prescriptions because of costs. Studies have shown CRN to be present in 13-

25% of elderly beneficiaries, [2, 14, 65-69] and it is associated with a lack of prescription drug coverage and poorer health.[2, 65, 69-77] Low-income seniors are particularly vulnerable, as they are disproportionately affected by disease burden (including being prescribed more medications than younger adults). Among chronically ill beneficiaries, 32% report skipping or reducing doses or not refilling a prescription due to cost. 30-50% of those who are also low income do not take drugs as prescribed due to cost.[78] Beneficiaries in poorer health have more, persistent CRN over time.[79]

CRN before Part D

In a synthesis of published literature about CRN before Part D was implemented, increased cost-sharing was associated with decreased adherence and higher likelihood of discontinuing therapy,[80] for both chronic and symptom-management medications.[81] One study examining the use of two different drug types (β-blockers and statins) found a different effect of copayment/coinsurance, which was medication-dependent.[82, 83] Adherence to new statin therapy (a more expensive drug) was reduced due to cost-sharing and coinsurance.[83] Sudden shocks to out-of-pocket spending (synonymous to doughnut hole design) can double the risk of stopping a statin. However, adherence even before cost-sharing was relatively low (56%), and adherence was not reduced for statin initiation after myocardial infarction.[83] In contrast, there was only a temporary drop in adherence to β-blockers after the copayment policy was put into place, but overall use was not affected by copays.[82] In contrast to copays reducing adherence, substitution policies in which a generic drug is used in favor of a brand-name drug, can reduce costs without the drop-off in adherence.[84, 85] Higher copays have also been associated with using fewer prescriptions.[16, 24] In summary, there is good evidence that out-of-pocket medication expense can decrease use of the medications themselves. Indeed, the goal and expectation of Part D was to improve access to medication, thereby decreasing CRN. Unfortunately, given the potential barriers to enrolling in a lowest-cost plan, a substantial proportion of beneficiaries may have out-of-pocket costs that would serve as a barrier to filling prescriptions, the precise reason Part D was implemented. As such, they may experience higher CRN.

Prevalence of CRN after Part D

Multiple studies have found that, even after Medicare Part D, CRN remains a concern for some Part D beneficiaries. In a study using MCBS data to examine rates of self-reported CRN among beneficiaries before and after Part D, Madden, et al. (2008) found that the overall prevalence of CRN significantly decreased after Part D, though the absolute change was small (from 14.1% to 11.5%). This trend did not hold for the sicker subgroups, including the disabled; those in fair to poor health;

and those with 4+ comorbidities.[86] Zhang, et al. (2010) assessed overall adherence (not CRN) using the medication possession rate (MPR) among MA-PD enrollees. They find that adherence rates (MPR>80%) improved post-Part D, with the largest improvement being for previously-uninsured individuals (average change = 13.4 percentage points). However, the improvements were smaller for individuals with previous drug coverage, ranging from 4-7 percentage points.[87] Of note, even the post-Part D adherence rates were still considered sub-optimal, even among the previously-insured. Other studies find that CRN among Part D beneficiaries varies from 12%-20%, as compared to a maximum of 25% before implementation. [14, 35, 51, 86] In contrast, only 8% of those with employer-sponsored benefits and 12% of those with VA drug benefits report experiencing CRN.[14, 35] Additionally, 8.7% also report foregoing basic needs to get medications.[86]

Health outcomes

CRN may also have significant adverse effects on patient health, although results overall are mixed.[80] Restricting medications due to cost is associated with a significant decline in self-reported health status over two years as compared to those who had not restricted medications.[5] Negative health outcomes due to cost-sharing can be seen across diseases. In individuals with cardiovascular disease, higher rates of angina, nonfatal heart attacks and strokes were reported as a result of CRN.[5] Patients with asthma experienced more frequent acute exacerbations after copay increases for their asthma medications.[88] Restricted medication access has even been linked to increased morbidity.[4] Among Medicare beneficiaries with diabetes, waiving cost-sharing for ACE-inhibitors was associated with increased life-expectancy.[89] In contrast, studies by Schneeweiss, et al have examined the effects of various cost-sharing arrangements and concluded that well-designed policies have the ability to save money without adversely affecting patient outcomes.[83, 84, 90] While the relationship between cost-sharing and health outcomes may not generalize to all populations, it appears that there can be a negative impact on the health of diabetes patients due to medication cost-sharing.

Health services utilization

Higher medication cost-sharing is associated with increased use of health services across studies.[80] Drug costs and formulary restrictions in particular can have an impact on an individual's use of health services. Medicare+Choice beneficiaries with a cap on their drug benefit—increasing cost-sharing when the gap is hit— used fewer prescription drugs to treat their chronic conditions, but had higher rates of emergency department visits, nonelective hospitalizations, and death.[4] Increases in drug cost-sharing are also related to medication adverse events. One study of Canadian elderly found

that a new drug policy with cost-sharing requirements significantly reduced essential drug use, while increasing acute care hospitalizations, long-term care admissions, and ED visits.[6] However, increased cost-sharing is not always associated with increased hospitalizations;[85] increased cost-sharing can also be associated with more physician visits.[91]

Conceptual model

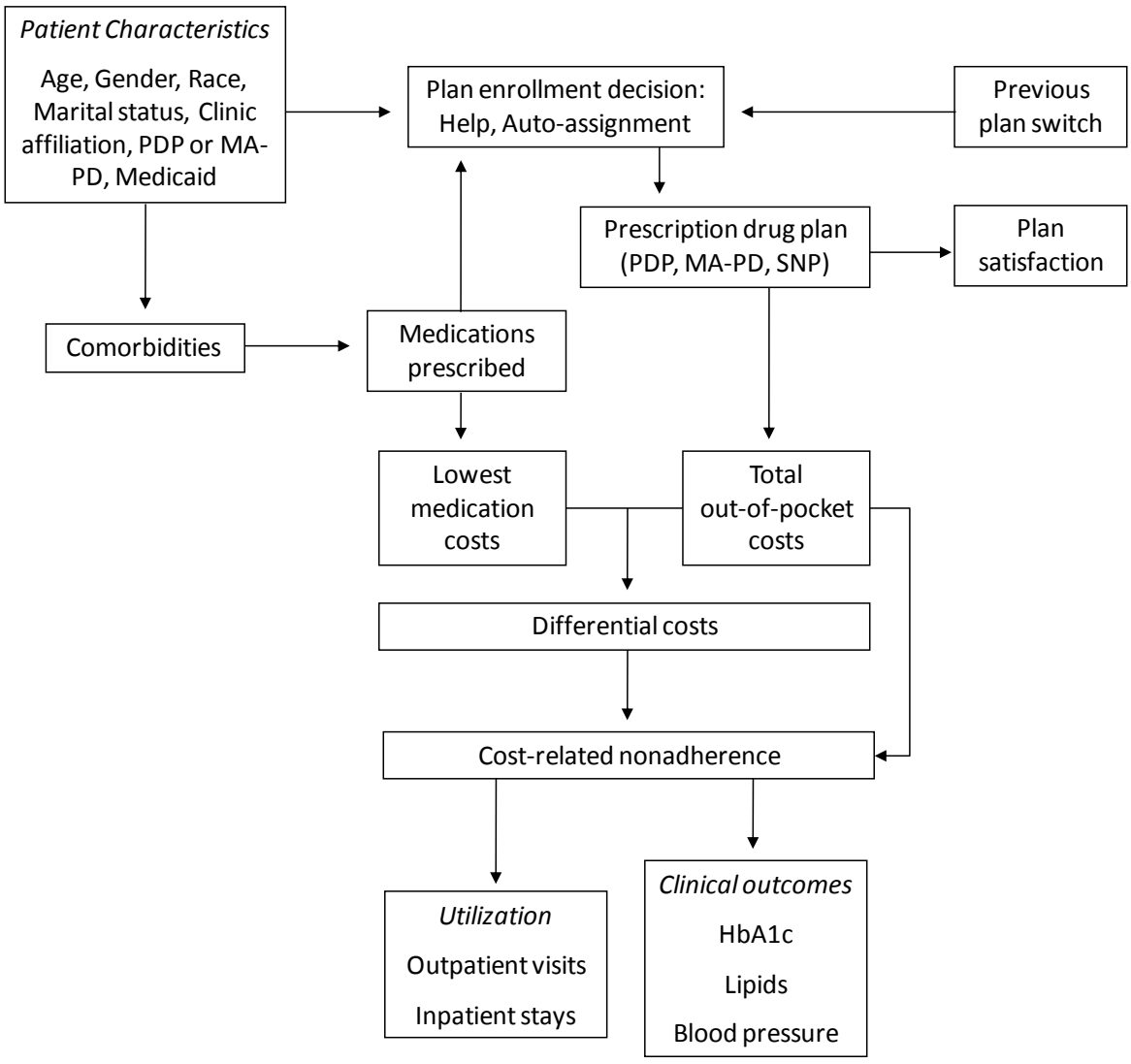
Early empirical results suggest that Part D is having success in reducing economic barriers to obtaining medications. Since policy implementation, beneficiaries have increased drug use and decreased prescription drug spending.[15, 27-29, 31] Recent research suggests that many beneficiaries may not be enrolled into lowest-cost plans given the way in which Part D was implemented, namely the multitude of plan options from which beneficiaries must choose, and the random assignment of duals. The potential for burdensome costs may result in CRN, which can in turn lead to worse clinical outcomes and increased use of health services.

Conceptual basis for research questions

Much of Part D's effectiveness for individual beneficiaries rests upon the assumption that they are able to choose and enroll into a plan that meets their needs. This can be defined as being in, or close to, a lowest-cost plan, which maximizes drug coverage while minimizing out-of-pocket expense. According to the Medicare Payment Advisory Commission, "Ideally, beneficiaries choose a plan that provides access to the medications they need at premiums and copays they are willing to pay, and then reevaluate the decision from time to time."[9] However, this may not be the case for all beneficiaries. This research will examine whether beneficiaries are getting into lowest-cost plans, either through making a plan choice or being randomly assigned to a LIS-plan.

The proportion of beneficiaries in lowest-cost plans is not currently well-understood. In addition, there is no research examining whether the random assigning of duals makes them less likely to be in a lowest-cost plan. Aim 1 will examine these two research questions. Further, it is not known whether the related unnecessary out-of-pocket medication spending may be affecting patient outcomes. There are no studies to date that examine the relationship between Medicare Part D plan enrollment, out-of-pocket spending, and ultimately patient outcomes; however, examining such outcomes in Part D is regarded as a next step for ongoing research.[15] Aim 2 will address this gap by determining the association between lowest-cost plan enrollment/differential costs and CRN. Then, the association between CRN and patient outcomes, including clinical outcomes and health services use, will be examined. Aim 3 performs the same analyses, but substitutes total out-of-pocket costs (rather than differential costs) as the key independent variable. Finally, Aim 4 will determine the association between switching plans and differential costs, plan satisfaction, and CRN. The proposed research will address these relationships as hypothesized in the conceptual model below.

Figure 5: Conceptual model



This model shows the potential pathways through which plan enrollment and subsequent medication costs can affect patient outcomes, including: CRN; clinical control of diabetes and related comorbidities; and health services utilization. Differential costs represent the "excess" expense that a beneficiary may be subject to if they are not enrolled in a lowest-cost plan. Depending upon the magnitude of these differential costs, CRN may result. This can then lead to increased utilization (measured as inpatient and outpatient visits) or worse clinical outcomes relevant to diabetes (HbA1c, cholesterol, and blood pressure).

Significance and implications

Contribution to the literature

Aim 1: To date, three studies have estimated the proportion of Part D beneficiaries in the lowest-cost plans.[37, 38, 56] Gruber, et al. (2009) found that only 6-9% of beneficiaries were enrolled in lowest-cost plans with absolute differential costs between $360-$520.[38] They suggest that "choice across such a wide range of Part D plan options may not be in the best interest of beneficiaries who are looking to maximize their savings."[38] In a longitudinal study using prescription drug records from 2005 (pre-Part D), Abaluck & Gruber (2009) examine drug utilization from that year and a Part D beneficiary's initial plan choice. They find that only 12.2% of their sample chose the lowest-cost plan, and participants could have saved 30.9% of their Part D expenditures by being in a lowest-cost plan instead.[37] Patel, et al. (2009) evaluated a tool that assisted Part D beneficiaries in PDP selection during open enrollment.[56] They measure the "potential annual cost savings" that would be incurred by being in a lowest-cost plan. Cost savings are defined as the cost of staying in the current PDP in 2008 minus the cost of the least expensive PDP in 2008, without making any drug changes and using the online plan finder tool. It is therefore very similar to my differential costs measure. They find that only 10.3% of participants were enrolled *in* the lowest-cost PDP, with a median potential cost savings of $98. However, potential savings varied by clinical characteristics, with individuals taking less than 3 medications having a median of $79, and those taking above 7 medications having a median of $318, up to a maximum of $9849 (therefore a very skewed distribution of potential cost savings).[56]

The results of these three studies suggest that only a small minority of beneficiaries (6-12%) are in lowest-cost plans. The rest are paying more than necessary to obtain their medications, and these extra costs are often substantial. Aim 1 of this study will examine the same question and can add to this recent literature by corroborating these findings with a different study sample. This research will also add to the literature in this area by reporting the results of a survey question that directly asks participants how they chose their plan at the start of the benefit. This open-ended question provides insight into the ways in which beneficiaries are making enrollment decisions. Additionally, I collected data about whether participants had help choosing plans and if so, who helped them. These types of details concerning plan enrollment have not yet been reported in the literature.

Aims 2 & 3: These aims examine whether patients' medication-related costs (i.e., being in a lowest-cost plan, differential costs, and total out-of-pocket-costs) are associated with CRN, clinical

outcomes and health services use. Yang, et al. (2009) conducted a study in which they examined which patient characteristics were significantly associated with nonadherence among Part D beneficiaries with diabetes. Their results show that being younger (<65 years old), Black/Hispanic, female, and sicker, were associated with a greater likelihood of being nonadherent to oral hypoglycemic agents.[92] However, this study examined a measure of general adherence, rather than CRN. This dissertation can add to the current literature by examining CRN among Part D beneficiaries with diabetes, and will also examine demographic predictors that may predict CRN. The second part of Aims 2 & 3 address the relationship between CRN and health outcomes as a result of Part D policy implementation. To date, there is little empirical research to support the presumed association between prescription drug coverage and health outcomes. It is important to understand the longer-term effects of Part D, by examining whether the policy can improve quality of care and subsequent health outcomes.[12] Kahn, et al. (2008) try to address this gap in the literature by examining the effect of prescription drug insurance on health outcomes (as measured by self-reported health status) in an elderly, nationally-representative sample, and find no significant relationship. However, this study used pre-Part D data.[93] This study adds to the literature by examining the impact of Part D enrollment decisions on patient-level outcomes, including CRN, clinical outcomes, and health services utilization.

Aim 4: This aim examines plan switching. In the published literature, it is clear that rates of switching are low.[14, 46] More specifically, Patel, et al. (2009) find that, despite the assistance offered to switch plans, only 44.7% of the 123 participants eligible to switch plans did so. Those who switched realized significantly higher cost savings than those who did not switch.[56] This research can add to the literature by examining the potential impact of previous plan switches as they may relate to differential costs, CRN, and current plan satisfaction.

Diabetes as a disease model

Diabetes will be used as a disease model because of its prevalence, morbidity, mortality, and cost. Diabetes is a metabolic disorder in which hyperglycemia results from defects with insulin secretion and/or insulin action. In 2005, 20.8 million people, or 7% of the population, had diabetes. However, 6.2 million of these people have not yet been diagnosed with the disease.[94] The elderly are disproportionately affected by diabetes. Among this age group (60+ years old), 10.3 million people (20.9%) have diabetes. The prevalence of diabetes among Medicare beneficiaries increased 36% between 1993 and 2001.[95]

Diabetes results in extensive morbidity and mortality. In 2005, the age-adjusted diabetes death rate was 24.6 per 100,000 for the United States, and 26.0 per 100,000 in North Carolina.[96] Clinical outcomes (blood glucose, blood pressure, lipid levels) are sensitive to CRN. Moreover, poor adherence to oral antihypoglycemics has been associated with poorer patient outcomes, including higher: A1c and LDL-C values; rates of hospitalization,[97] and even mortality.[98]

In 2002, diabetes accounted for $92 billion in direct medical costs.[94] The costs associated with treating diabetes are significant for Medicare (CMS). In 2001, 30% of high-cost beneficiaries had diabetes, as compared to 16% of low-cost beneficiaries.[99] Diabetes drugs have recently overtaken cholesterol drugs as the leading drivers of pharmaceutical spending growth. Spending on diabetes drugs increased 12% in 2007, mostly due to a shift in newer expensive drugs (and the corresponding new generic lipid-lowering agents).[100] This trend shows no signs of slowing, as there are multiple new diabetes medications, all of which will cost more that older treatment options (and are not available generically).[101]

In addition to the prevalence, morbidity, and costs, diabetes is also a logical disease model in which to study Part D. There is wide variability in medication coverage across plans for oral hypoglycemic agents. In an analysis of the variation in formulary coverage among 13 of 14 benchmark LIS plans in NC (2007), the coverage of diabetes prescriptions ranged from 44% to 94% (mean = 0.61, SD = 0.15) [unpublished results]. Many glucose lowering agents do not have a generic equivalent, which can increase costs for beneficiaries because brand-name drugs are more expensive to obtain (for both copay and coinsurance amounts).

Policy implications

The proposed study addresses several important policy questions for CMS. In a 2006 report for a bipartisan health policy conference, it was said that, "Ultimately, [Part D's] success will be judged by *whether beneficiaries enroll in plans that meet their needs* and whether the program's costs are held within reasonable limits."[102] The results of this study directly address the first part of that statement, by examining the impact of Part D enrollment policies on the beneficiary experience and subsequent outcomes. This study will address whether beneficiaries are able to navigate into plans that adequately meet their needs, assessed by whether they are in or near lowest-cost plans. If there is evidence that lowest-cost plan enrollment is directly associated with CRN, or indirectly associated with clinical outcomes, or health services utilization, CMS will be better informed as to whether Part D is achieving its potential to improve the quality of care and health of its Medicare beneficiaries.

For the dually eligible, study results may have implications for the current random auto-enrollment process. If a significant proportion of beneficiaries are not in lowest-cost plans, CMS has the ability to facilitate beneficiary-centered assignment, rather than random auto-assignment, to ensure that enrollees are in a lowest-cost plan. MedPAC is currently evaluating the impact of beneficiary-centered assignment on medication access in a study for CMS.[8] CMS could facilitate enrollment into an individual's lowest-cost plan based on their current medication list. Although the use of current medications may not be ideal,[50] it is the best directed enrollment mechanism available to date. This could be done using administrative prescription drug event data, matched to formulary information, for each beneficiary.

For other (non-dual) beneficiaries, study results may also be relevant to enrollment processes. CMS recognizes that there are "potentially too many choices" for beneficiaries with regard to plan selection and have responded by slightly reducing the number of plan offerings by rejecting more duplicate applications.[103] However, there is a potential for more action to be taken in this regard. There has been some interest in simplifying Part D choices such that the program becomes more consumer-friendly. This could be achieved in multiple ways: (1) offering the drug benefit under original Medicare, either in conjunction with or replacing the private Part D market; (2) limiting the number of plans or standardizing the offerings.[12] Some research suggests that restricting a beneficiary's choice set may better serve their interest.[37] As an alternative to reducing plan offerings or simplifying choice, CMS could enhance and improve upon decision-making tools for seniors and their caregivers. If this study indicates that a large proportion of beneficiaries are enrolling into non-lowest-cost plans, CMS can develop further education and outreach materials, or improve their dissemination and use.

This will be the first study to enroll a cohort of patients with Medicare Part D and to be able to link their plan choice with CRN, clinical outcomes, and health services utilization. The results of this study can also be used to extend what is currently known about Medicare Part D with regard to medical costs and clinical outcomes. Until June 2008, drug claims data were being used for payment (administrative) purposes only. While Part D data have recently been made available to researchers, there is currently no ability to link individual beneficiaries to specific plans.[104] While claims data are available, this study is unique in its ability to link individual-level plan and cost data with medical record data, including clinical outcomes. More broadly, the evaluation of Medicare Part D can teach us valuable lessons in the context of health reform. The newly-enacted legislation includes the provision of insurance partly through health insurance exchanges at the state level, called "American Health Benefit Exchanges." The structure of these Exchanges bears many similarities to the way in

which Part D is delivered. Specifically, individuals can purchase insurance in the Exchange marketplace, in which the federal government will contract with private insurers to offer at least two plans in each Exchange. Plans offered will be required to meet a minimum standard (such as the standard benefit in Part D). Competition is a hallmark of the functioning of Exchanges, and is intended to keep the price of coverage down. In these key aspects, the delivery of health insurance will be similar to the delivery of prescription drug insurance under Part D. Therefore, it is crucial to understand the ways in which policy implementation of Part D is having an impact on beneficiaries. The observed complexities associated with plan choice, information overload, and enrollment decisions have the potential to carry over into the new health insurance marketplace as well. Given this, it is of paramount importance to understand the ways in which Part D may affect beneficiary enrollment decisions, out-of-pocket costs, and patient outcomes. This study will directly address this knowledge gap.

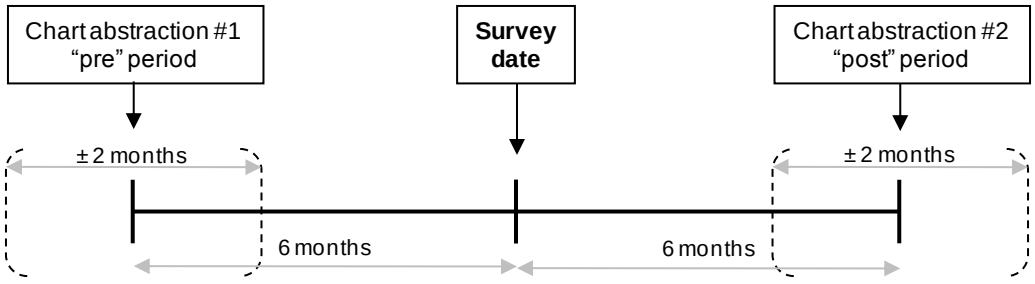
CHAPTER 3: METHODS

Study design

This study examined the impact of lowest-cost plan enrollment, differential costs, and total out-of-pocket costs on patients' CRN, clinical parameters, and health services utilization. This was conducted among elderly Medicare Part D beneficiaries with diabetes receiving primary care in the General Internal Medicine or Family Medicine practices at UNC-Chapel Hill. The study had two parts. First, eligible patients were invited to participate in a survey about their Medicare Part D plan (i.e., current plan, whether they switched, how they enrolled, satisfaction, and CRN (Appendix A).

Second, for patients who returned HIPAA authorization, we abstracted chart data from UNC's electronic medical record (WebCIS), including prescribed medications, clinical parameters, and health services utilization. Data were collected at baseline (date of survey) as well as 6 months before and after the survey date (pre and post period, retrospectively). We extracted clinical and utilization data during a $\pm$ 2-month window surrounding both the pre and post period date (Figure 6). In addition, we estimated actual and lowest possible out-of-pocket medication costs for each subject's prescribed drugs using a publicly-available online CMS tool. The study was approved by the UNC Public Health-Nursing IRB; The Division of General Medicine & Clinical Epidemiology Research Committee; and the Family Medicine Center Studies Oversight Committee.

Figure 6: Data collection



Study sites

Participants included patients with diabetes who received care at one of two primary care clinics at UNC Chapel Hill: the Internal Medicine Clinic or the Family Medicine Center. Each of these practices maintains a diabetes registry that is used for clinical and quality improvement purposes.

Study sample

Participants were eligible for the study if they met the following inclusion criteria: (1) received primary care from UNC Chapel Hill's General Internal Medicine or Family Medicine practices and (2) had ≥ 1 visit in the 12 months preceding receipt of registry data, to ensure that patients were currently receiving care at UNC; (3) had a diagnosis of diabetes, as defined by being in the General Internal Medicine or Family Medicine Diabetes Registries; (4) were ≥ 65 years old. Potential participants were excluded if they were: (1) eligible for Medicare due to disability status alone (because they are likely to be systematically different from elderly beneficiaries, including more prescribed medications;[14, 105] (2) non-English speaking; (3) unable to participate on a phone interview due to a hearing or cognitive deficit; or (4) non-community dwelling. For potentially-eligible patients, we obtained basic contact information from the diabetes registries. Eligibility was confirmed during the initial telephone contact.

Data collection procedures

(1) Overview of data sources

This study combines data from three distinct sources: participant surveys; publicly-available Part D plan data; and UNC medical records. For UNC medical record data, I manually abstracted medication data for use in CMS' online Prescription Drug Plan Finder (PDPF) tool. This is a website into which a beneficiary can enter all of their medications to obtain annual cost estimates for all plans available in their area. Then, I worked with the Carolina Data Warehouse for Health (CDW-H) to abstract all other clinical and utilization data elements. All data sources were merged to create an analytic file with individual-level, longitudinal clinical data and cross-sectional survey and cost data. All registry data, recruitment call logs and tracking, and survey data were stored in a Microsoft Access relational database. Ultimately, data from all sources were linked to a final de-identified dataset that resides on a secure server.

(2) Recruitment process

The protocol was specifically designed to minimize the burden on both Internal Medicine/Family Medicine staff and patients, i.e., there was no data collection in the clinics. Rather, all data were collected by telephone or electronic medical record abstraction.

1. The General Internal Medicine and Family Medicine diabetes registries were used to obtain basic contact information (name, phone number, address) for all patients ≥ 65 years.
2. Potential participants were mailed a letter on Internal Medicine or Family Medicine letterhead, signed by the clinic director (Appendix B; Appendix C). This letter explained the study and stated that potential participants have the ability to opt out of being contacted by calling a toll-free number. The introductory mailing included the letter, 2 copies of a HIPAA authorization form (Appendix E), and a handout of sample Part D cards to help participants identify their Part D plan (Appendix D), and a $5 gift card to either WalMart or CVS. Letters were sent in waves of 60 per mailing, so that the initial phone contact could occur within 1-2 weeks of receiving the letter.
3. Potential participants were contacted by phone after receiving the introduction letter, unless they called the toll-free phone number to opt out of the study. If potential participants were not contacted after 6 attempts, they were classified as unable to be reached.
4. Verbal consent for survey participation was obtained by asking individuals whether they agree to participate at the start of the phone call. The beginning of the phone script contained standard consent language as is used in IRB written consent forms. For those participants who verbally consented to participate in the phone interview and had Part D, a short telephone survey was conducted.
5. Part D plan information was obtained from participants, via the process described in the *(3b) Obtaining* plan information section.
6. Upon completion of the phone interview, participants were asked for consent to access their medical record. If they agreed, they were asked to return a signed copy of the HIPAA authorization form in the addressed, stamped envelope. Study participants who had not returned HIPAA forms after two weeks received follow-up phone calls until the forms were received. We mailed new HIPAA forms when requested.
7. After receipt of the HIPAA form, manual and electronic chart abstractions were conducted using data from UNC's electronic medical record, using either WebCIS or the CDW-H.

8. For each individual, total out-of-pocket costs and lowest medication costs for all prescribed medications were estimated using CMS' online Formulary Plan Finder tool (Appendix G).
9. All data (survey, WebCIS, CDW-H, PDPF) were merged into a single database that was housed on a secure server for analyses.

(3) Telephone surveys

Telephone surveys, conducted by trained interviewers, were designed to take 10-15 minutes. The survey (Appendix A) assessed the following: (a) satisfaction with current plan; (b) whether they have switched plans in the past year and if so, why; (c) how they initially chose a Part D plan; (d) whether they had help choosing a plan and if so, from whom; (e) whether they receive extra help (low-income subsidy); (f) cost-related nonadherence; (g) whether they substitute generic equivalents; (h) self-reported health status; and (i) the name of their current Medicare Part D plan. Operational definitions for all variables are presented in the *Variables and measures* section. When possible, validated instruments were used.

Survey methodology used Dillman's tailored design method (2000) to maximize response rate by evoking respondent trust and social exchange principles for survey design.[106] Participants should feel that the reward for responding will outweigh anticipated costs, and this can be accomplished through development of the survey specifically with elderly Medicare respondents in mind. One way to establish trust is to provide the incentive in advance.[106] The incentive for participation in this study was a $5 gift card to either CVS or WalMart, included with the initial introduction letter mailing, rather than after survey completion. Phone interviews are considered an ideal mode of obtaining information from elderly participants.[106] Survey questions were also written to be mindful of low education levels.

(3a) Survey pilot testing

Based on a pilot test with 20 participants, we modified the survey. Our main concern was that participants had trouble identifying whether they had Part D and/or which plan they had. Thus, the interview script was modified to more clearly describe Part D (See *(3b) Obtaining plan information* section). In addition, in the introduction letter we included a handout containing pictures of sample cards that highlighted where to find the contract and plan identification number (Appendix D). Another change that arose out of pilot-testing was the issue of switching to generics. Many participants mentioned that they asked their physician/pharmacist to take generics wherever possible.

This was added as a separate question so that it can be quantified in the analyses. Other small modifications included shortening the introductory script and adding a prompting question to help participants remember receiving the letter. The time to initial contact was also modified from two weeks to one week to help with participant recall.

(3b) Obtaining plan information

Given the importance of accurately identifying participants' plan name *and* contract/plan ID numbers, as described above, we included a handout of sample cards in the initial mailing with MedicareRx logo and ID numbers were located. During the interviews, we began by asking whether participants knew the name of their plan using the following questions: (a) What does it say at the top of your card? (plan name); (b) Do you see the MedicareRx logo on your card? (to ensure it was a Part D plan/card); (c) What are the plan and contract ID numbers on the bottom of the card? (these uniquely identify a specific plan within a given company's set of up to 3 plans). We verified the accuracy of the plan information (plan and contract ID numbers) from their Part D card using lists of available PDPs/MA-PDs/SNPs in North Carolina. If the participant stated that they did not keep their card, but rather a family member or pharmacist had the card, we contacted the pharmacy/family member with verbal permission from the participant. In many cases, multiple phone calls were needed to obtain plan information, for instance if the participant did not have their card at the moment, or if a family member kept the card.

In a few cases for individuals with MA-PDs, WebCIS was used to verify plan identity. Because UNC Health Care bills Medicare Advantage for medical care, this information was kept on file in WebCIS. In a small minority of cases, the information obtained from multiple sources conflicted. In these cases, the order of information used was: (1) Survey (either study participant or family member); (2) WebCIS; (3) pharmacy. The pharmacy was a difficult way of obtaining exact plan information because they do not keep actual plan names and ID numbers on file. Rather, they send their claims to an intermediary pharmacy benefit manager, which uses a different ID numbers for each plan. Finally, in some cases we could elicit the only the contract (company) ID, but not the specific plan ID. Because a company could offer up to three specific insurance products, we averaged the costs of the available products offered by that company.

(4) Medical record data

WebCIS is UNC's electronic medical record, from which the clinical and utilization variables were abstracted (Table 2). The data was obtained in two ways: via manual abstraction of the medical record (for medications and basic demographics), and the CDW-H for all other data elements.

(4a) Manual abstraction of WebCIS

I manually abstracted active medications, Medicaid status, and zip code from WebCIS for each participant who returned a signed HIPAA waiver form. Active medications include all Part D medications that are prescribed to the participant as of their survey date. This manual abstraction was necessary so that medications could be entered in to the CMS online Prescription Drug Plan Finder (PDPF) tool to obtain all cost estimates. By performing manual abstractions, I was able to see all physician notes to the pharmacist about the prescribed medication, as well as sort through active and inactive medications. Sorting through inactive medications was necessary when abstractions were occurring after the survey data if a participant had an office visit, with medication changes, since the survey date. In this case, it was necessary to obtain the inactive medication list to ensure that the active medication list *as of the survey date* was used for all participants to ensure comparability. This ensured that most accurate prescribed medication was entered into the PDPF tool as of the survey date, from which costs were calculated.

(4b) Carolina Data Warehouse for Health (CDW-H)

The CDW-H is a retrospective record of cleansed data that comes from multiple UNC Health Care Systems electronic databases. I requested the data elements (clinical parameters, utilization, comorbidities, demographics, whether died during study period) and the medical record numbers for the participants who signed HIPAA waiver forms. The programmer provided me with data sets at three points during the study. Per the user agreement, I transferred all of my data to the medical school (CDW-H) server, linked the files, and performed analyses with the data in this location. The final, de-identified dataset was transferred back to the Sheps Center server. Permission to use the CDW-H was granted from the Operations Committee.

(5) Cost calculations using CMS data

The PDPF tool was used to calculate both actual medication costs and lowest medication costs for each individual. In 2008, out-of-pocket costs were added to the calculator tool, so that an individual can put in their full list of medications and find out their lowest-cost plan, as well as the annual costs for each of the plans offered in their county (PDPs, MA-PDs, and SNPs). In consultation with clinical pharmacists at UNC, a set of decision rules were developed to ensure consistency in the way in which medications were entered into the PDPF tool (Appendix F). Decisions were made to provide conservative cost estimates. For example, all medications prescribed on an "as needed" basis were entered as only being filled once per year. This way, we captured whether the medication was on formulary, but maintained a conservative cost estimate. All costs are calculated from prescribed medications, rather than from filled prescriptions.

The following steps were followed in using the PDPF tool:

1. Navigate to www.medicare.gov/MPDPF/Home.asp
2. *Step 1: Select a search option:* The "General Plan Search" option was selected because information from an individual's Medicare card was not obtained.
3. The following were used as inputs in *Step 2: Enter the requested information*:
    a. Zip code: person-specific, obtained from WebCIS
    b. Age range: not selected (no input is required)
    c. Health status: not selected (no input is required)
    d. "Do you currently have prescription drug coverage:" For individuals with a MA-PD or SNP, the option "yes—Medicare Health Plan" was selected. For those with PDPs, "I don't know" was selected. This selection allowed for easier access to MA-PD plans, as PDPs were the default output unless this option was specified for MA-PD participants.
    e. "Do you have any other health insurance coverage:" This was automatically filled in for MA-PD participants, and "I don't know" was selected for PDP participants.
    f. "Did you get a letter from Medicare or the Social Security Administration (SSA) that said you are either eligible for or qualified for extra help paying for your Medicare Prescription Drug Plan costs?:" This answer was person-specific, and varies based on

Medicaid status. Medicaid status was assessed from the registry and confirmed from WebCIS data. For those who are dually enrolled into Medicare and Medicaid, the "yes" option was selected, then "Medicare in response to "Who sent you the letter?" Lastly, in response to "What kind of help do you get?" "Medicare and Medicaid" was selected. For those who are not dually-eligible but responded that they received extra help, the "Social Security Administration" option was selected in response to the question "Who sent you the letter?" For these participants, the following options were selected for the subsequent pop-up questions: Notice of award→partial help→50%.

g. *Step 2a: Select county*: For individuals who live in a zip code that spans more than one county, their appropriate county was selected (county information obtained from manual WebCIS abstraction)

h. The individual's Medicare Advantage plan was selected on the next page for those with MA-PD/SNP plans.

4. *Step 3: Review Current Coverage and Consider Options*: click continue to proceed with entering medication list

    a. Under "Get Drug Costs for Available Plans," the option "Enter my drugs" was selected.

    b. Each of the Part D drugs from an individual's drug list was entered into this query.

5. Costs were calculated with the option "Use lower cost generic drugs when available" both checked and unchecked. This step then shows which of the drugs are brand name only, generic, or have a generic equivalent. Sensitivity analyses will determine whether this has a significant impact on different cost estimates.

6. The dosages and quantity/month (days supply) were entered as taken from the medication list. The medication list was abstracted from WebCIS for the participant's survey date. In many cases, the abstraction occurred after this date (because we had to wait for HIPAA to be returned). In these cases, I retrieved the inactive medications list to ensure that the medications entered into the PDPF tool were the medications that the participant was taking as of their survey date.

7. The security password was set as Jan 1, 1900 for all participants. This returns a medication list-specific ID number, which can be used to pull up an individual's medication list upon revisiting the site.
8. In response to the question "Do you want to select a specific pharmacy or pharmacies from which you prefer to purchase your drugs?" "no" was entered. This allows for the largest array of plan options to be returned and assumes that the individual is filling their prescriptions at a retail pharmacy (and not via mail-order).
9. The personalized list for an individual was returned at this point. This returns the information: Plan name and ID numbers; Estimated annual cost, which included the monthly premiums.
10. The plan/contract ID and estimated annual costs were recorded for both the actual plan and lowest-cost plan.

Variables and measures

Data for this study came from three sources: participant interviews, CMS' online PDPF, and the UNC medical record (via WebCIS abstraction or CDW-H) (Table 2). Notably, data obtained from the medical record were collected at two time points: six months before and six months after an individual's interview date, with a 2-month window around each of those pre and post dates (Figure 6).

Table 1: Variables used in multivariate regressions

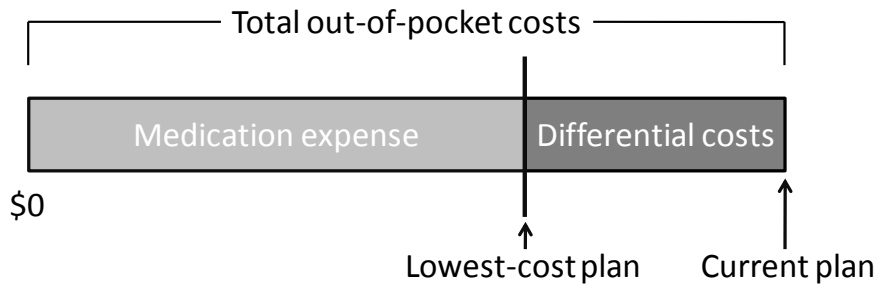
Dependent Variables			
Lowest-cost plan enrollment	1	PDPF	Being in a plan with costs within 10% of the annual out-of-pocket costs in a lowest-cost plan
Differential costs	4	PDPF	Total out-of-pocket costs - lowest costs
Cost-related nonadherence	2,3,4	survey	Self-report of experiencing any of 3 cost-related behaviors
Clinical outcomes		CDW-H	
Diabetes	2,3		HbA1c
Blood pressure	2,3		Systolic & diastolic BP
Lipids	2,3		Total; LDL; HDL; triglycerides
Self-reported health status	2,3	survey	Single-item question in which participants rate their general health
Health services utilization		CDW-H	
Inpatient stays	2,3		Number of stays to UNC hospital
Outpatient visits	2,3		Number of visits to any UNC clinic
Plan satisfaction	4	survey	Self-reported satisfaction with current plan (1-5 Likert scale)
Key Independent Variables			
Dual eligibility	1	WebCIS; CDW-H	Receives Medicaid (full dual status)
Lowest-cost plan enrollment	2	PDPF	Being in a plan with costs within 10% of the annual out-of-pocket costs in a lowest-cost plan
Differential costs	2	PDPF	Total out-of-pocket costs - lowest costs
Total out-of-pocket costs	3	PDPF	Total annual medication expense in beneficiary's current plan
Previously switched plans	4	survey	Yes or no (in past year)
Control Variables			
Medication expense	1,2,3,4	WebCIS; PDPF	Annual medication expense in beneficiary's lowest-cost plan
Comorbidities	1,2,3,4	CDW-H	Charlson comorbidity index
Plan enrollment	1,2,3,4	survey	Informed choice; random choice; insurance agent
Patient characteristics			
Age	1,2,3,4	CDW-H	Calculated from birth date, at time of survey
Gender	1,2,3,4	registry	Male or female
Race	1,2,3,4	CDW-H	White or non-white
Marital status	1,2,3,4	CDW-H	Married or single
Dual eligibility	2,3,4	WebCIS; CDW-H	Receives Medicaid (full dual status)
Clinic affiliation	1,2,3,4	registry	Internal Medicine or Family Medicine
Plan type	1,2,3,4	survey	Medicare Advantage or stand-alone PDP

Cost variables

Definition of a Part D drug: The medication list was obtained from WebCIS via manual chart abstraction. Only Part D medications were used, according to the standard definition of a Part D drug: "a Part D drug is a drug that is approved by the Food and Drug Administration, for which a prescription is required, and for which payment is required under Medicaid. Biological products, including insulin and insulin supplies, and smoking cessation drugs are also covered under Part D."[107] Prescription drugs not covered by Part D were excluded, such as those used for hair growth, fertility promotion, and drugs covered by Medicare Parts A and B. This definition for medication regimen included most—but not all—chronic medications (for example, benzodiazepines are excluded from coverage) that are available by prescription only. Over-the-counter medications, vitamins, and herbals were excluded, per the Part D regulations. In addition, we decided to exclude antibiotics that are clearly used in the short-term only. Medications that were prescribed "as needed" were entered into the PDPF tool as being filled only once per year, rather than monthly. These considerations produced a conservative estimate of medication costs. (See Appendix F for all decision rules).

Standardizing cost estimates to 2009: Data related to costs were collected in 2008 and 2009. However, out-of-pocket costs can vary across years, even if the medication list and PDP were unchanged, because there may be differences in formulary and benefit design across years. Therefore, it was necessary to standardize cost estimates across time. This was done using data collected by the SeniorPharmAssist program in Durham, NC during open enrollment for the upcoming 2008 benefit period. We examined cost estimates for individuals in 2008 and 2009, holding person, plan, and medication list constant. A median percentage increase from 2008 to 2009 was calculated, and this inflation factor was applied to all individuals in the study sample for whom data were collected in 2008.

Figure 7: Definition of cost variables



All cost variables were estimated by entering the WebCIS medication lists into the PDPF tool. These calculations were each made twice: once assuming that prescriptions were filled as written ("as written"), and again with all possible generic substitutions ("generic").

Total out-of-pocket costs: This is a continuous variable that indicates the total annual medication expense in beneficiary's current plan. (See *(3b) Obtaining plan information* section for details on self-reported plan information). This assumes filling all Part D medications as prescribed annually. This variable was obtained using the Medicare Prescription Drug Plan Finder tool, and was calculated as both "as written" and "generic". It is used at the key independent variable in aim (3a).

Medication expense: This is defined as the annual medication expense in a beneficiary's lowest-cost plan. It was used as a control variable as a measure of the expense that would be required

to fills all medications prescribed in WebCIS. It was used assuming "as written" fills in the "as written" models, and assuming all possible generic substitutions in the "generic" models.

Lowest-cost plan enrollment: For the medications prescribed to an individual in WebCIS, we used the PDFP to calculate the total out-of-pocket costs (including premium) of: (1) a lowest-cost plan in which a person could be enrolled (there may be more than one lowest-cost plan) and (2) the plan in which they were actually enrolled. Based upon the difference of these two costs, we created a dichotomous variable to reflect whether the individual was in a plan within 10% of the annual out-of-pocket costs in a lowest-cost plan. This variable is used as the dependent variable in aim (1) and as the key independent variable in aim (2a).

Differential costs: I calculated the difference between total out-of-pocket costs and the annual costs that would be incurred in a lowest-cost plan (using the PDPF tool). This continuous variable, which is measured in dollars, can range from $0 to thousands of dollars. This variable is used as the dependent variable in aim (1) and (4a) and as the key independent variable in aim (2b).

Other key dependent variables

Cost-related nonadherence (CRN): CRN was based on a previously validated measure of medication adherence that was added to the MCBS in 2004 (*Access to Care* section).[65] The original measure was developed for a large national survey[2, 67] and showed good construct validity and test-retest reliability.[2, 65, 108] We only asked questions that assessed cost-related reasons for non-adherence. These included: (1) skipping doses; (2) failing to fill/refill prescription due to cost; (3) taking smaller doses of meds to make prescription last longer. For each question, the respondent could answer: "yes, often," "yes, sometimes," or "no." I created a summary dichotomous measure in which a person was classified as having CRN if they answered affirmatively to any of the three questions.

Clinical outcomes: Three diabetes-related clinical outcomes were measured. First, glycosylated hemoglobin level (HbA1c) measures long-term (approximately 2-month) glycemic control. American Diabetes Association clinical practice recommendations recommends that A1c be measured twice yearly if controlled or quarterly if therapy has changed or not controlled. Second, I obtained systolic and diastolic blood pressure measures, which are generally taken at each clinic

visit.[109] Finally, I obtained data on low density lipoprotein (LDL) cholesterol, which is also recommended at least annually.[109] I chose these three measures because they are clinically important outcomes for patients with diabetes (i.e., associated with morbidity) and (2) it is reasonable to expect that there will be at least one measurement of each clinical value being collected per patient per year. As shown in Figure 6, we obtained all clinical parameters within 2-months of the pre and post period date. For participants with multiple lab values, they were all collected and averaged.

In primary analyses, all clinical values were used continuously to increase the ability to detect a significant effect. When using longitudinal data from both the pre and post periods, the difference between the two values was used as the dependent variable to detect whether a change occurred during the study period. While each of these values can be dichotomized based on current clinical guidelines, these analyses were considered secondary to the continuous difference variables.

Self-reported health status: The participant interviews asked: "In general, would you say your health is: excellent, very good, good, fair, or poor?" The responses were dichotomized as "fair" and "poor" versus "good," "very good," and "excellent."[110] The use of this single-item has been shown to be a good predictor of mortality,[111] hospitalizations, and outpatient visits.[110]

Health services utilization: There were two measures of utilization collected from the CDW-H: inpatient stays and outpatient visits that occurred during the study period. Inpatient stays was dichotomized to indicate whether the participant had any inpatient stays in the given time period. Outpatient visits was used as a continuous variable indicating the count of any clinic visit that a participant had to any UNC clinic in the given time period. Outpatient visits are not differentiated by type of clinic because I do not hypothesize that there are differential visits by clinic type, and I am not transferring outpatient visits to an estimated utilization expenditure (in which case clinic type would need to be taken into account). Both variables (inpatient and outpatient visits) were abstracted at two time points (6 months before and after interview). The variable was captured as number of visits in the 4-month time period (± 2 months from the 6-month pre/post date).

Plan satisfaction: Participants were asked, "How satisfied are you with your current Medicare prescription drug plan?" The responses were on a 5-point Likert scale ranging from 1 (very dissatisfied) to 5 (very satisfied). To be more consistent with the general measures of satisfaction that

have been reported in the literature to date, [25, 57] responses were collapsed into a dichotomous variable in which satisfied included those who answered either somewhat or very satisfied.

Other key independent variables

Medicaid status: This dichotomous variable uses data from both the registry and WebCIS. An individual is considered to have Medicaid if either the registry OR WebCIS (upon manual chart abstraction) indicates that they receive Medicaid. Any potential participant who received Medicaid is dually eligible, and (almost) all of these individuals were randomly auto-assigned to plans.

Previously switched plans: This dichotomous variable was based on participants' response to whether they had *previously* switched plans in the past year. For those participants who indicated having switched plans, they were also asked: (1) in which month the switch was made; (2) the reason for the switch (open-ended).

Control variables

Near poor: This is defined as having an income between 100-250% FPL. This variable is taken from the field in WebCIS to indicate whether a participant receives charity care. This variable is a dichotomous measure and is counted as yes if the participant was ever enrolled in the charity care program as of the chart abstraction date, even if the charity care has expired. This is because the incomes for this age group are unlikely to drastically change and we are more interested in developing a specific measure to indicate which participants are above the Medicaid threshold but still considered near poor.

Comorbidities: ICD-9 codes obtained from the active problem list in WebCIS were used to develop calculate the Charlson comorbidity index. This index is based upon the presence or absence of 17 comorbid conditions in medical record data, and was developed to predict one-year mortality based upon disease severity.[112] More specifically, I used the Deyo adaptation to the Charlson index, which is designed for use with administrative data.[113] Stata code for the Charlson index was adapted

from code written by Vicki Stagg and based upon a SAS coding algorithm published by Quan, et al. (2005).[114, 115]

Plan enrollment: We asked participants an open-ended question to ascertain how they chose a plan at the start of the benefit. Based on responses to this question, we created a 3-level variable that is used in multivariate models as a set of dummy variables: *informed choice*; *random choice*; *insurance agent*. These three categories are mutually exclusive and indicate whether participants considered any sort of individual medication need when deciding on a plan (informed choice); did not take medication need into account (random choice); or had the assistance of an insurance agent when enrolling (insurance agent).

Patient characteristics: Standard demographic variables were in the dataset, including: age, gender, race and marital status (dichotomized as married or single).

Clinic affiliation: This dichotomous variable represents whether the study participant receives care from the Internal Medicine or Family Medicine practices. It was flagged based upon the diabetes registry in which the participant was listed.

Plan type: This dichotomous variable denotes whether the participant was enrolled in a PDP or MA-PD. Those enrolled in SNPs and MA-PDs were grouped together, given that SNPs are a special type of MA-PD with a similar benefit structure.

Extra help: We asked respondents whether they receive extra help paying for their medications, which is also known as the low-income subsidy (see Appendix A for question). For participants who reported receiving extra help, this option was selected in the PDPF tool, so that these subsidies were accurately reflected when estimating their annual costs.

Risk aversion: Some beneficiaries may intentionally choose a more generous, but more expensive, Part D benefit in exchange for more comprehensive coverage. To capture this, we asked

whether participants generally receive vaccines/immunizations as a measure of risk aversion. This question was added to the survey mid-way through data collection.

Benefit type detail: These are a measure of plan generosity assigned by CMS based on the benefits offered by a particular PDP or MA-PD. The 4 possible categories, in order from least to most generous, are: defined standard benefits (exactly the same as the standard benefit); actuarially equivalent (equivalent to defined standard, but with different features); basic alternative benefits (generally have smaller deductibles); and enhanced alternative coverage (have additional premiums, associated with more generous coverage that is not subsidized by CMS). These 4 variables are used together as potential instruments in aims 2 and 3.

Sample size and statistical power

Sample size estimates were based on: α-level, the number of covariates used in multivariate analyses, anticipated effect size, and desired power. This calculation assumed a two-sided significance level of $\alpha=0.05$ and 80% power to detect differences in outcomes. A sample size calculation was performed using PASS software to determine the appropriate sample size needed to address my study aims.[116] These are generally divided by whether a linear or logistic regression model is used.

For linear regression models with differential costs as the outcome variable (aim 1b), a sample size between 118-172 is required to detect a significant relationship. This variation in sample size depends upon the number of regressors used and the effect size. The effect size (f^2) is analogous to the R^2 value in a multiple regression context. With 10 regressors in the model, 172 participants are needed with an R^2 of 0.1 and 118 participants are needed with an R^2 value of 0.15.[117, 118]

For aims (2a) and (3a), a continuous key independent variable (differential costs or total out-of-pocket costs) is used to predict CRN, a dichotomous variable. For these logistic regressions, a sample size of 140 achieves 80% power at a 0.05 significance level to detect an odds ratio of 1.7. This also assumes an R^2 value of 0.1.

Initial sample size projections estimated that we would have a sample size of approximately 400 participants. There were 984 potential participants between both registries (588 from General Internal Medicine and 396 from Family Medicine). We assumed that 25% of registry members did not have Part D and anticipated a 65% response rate based upon convention in other health services research surveys.[119] This gave us a projected sample size of 480 participants, though we anticipated a

final sample size around 400 participants after accounting for being unable to reach some patients and being unable to collect full Part D information from others. According to *a priori* power calculations, we expected to recruit enough patients to have adequate power to test the hypotheses in aims 1-4.

Statistical analyses

I have organized this section into two sub-sections, that is, analytical considerations that are relevant to more than one aim and those that are related to individual aims.

Analytical considerations across aims

I will begin by characterizing the sample using descriptive data. I used either t-tests (for continuous outcomes) or Pearson chi-square (χ^2) tests (for categorical outcomes). In the case of cells with low frequencies, a Fisher's Exact Test was used instead of the Pearson chi-square test. For variables that are not normally-distributed, I used a non-parametric approach (Mann-Whitney test).

Selection of control variables: Selection of control variables was driven by the conceptual model (Figure 5). The specific covariates included in each model are listed by specific aim, below. In addition, because site of enrollment (General Medicine versus Family Medicine) can represent unmeasured differences in patients, physicians, and organizations, I controlled for site in all analyses.

Approaches to non-normal data: Differential costs and medication expense were logged for use in linear regression models. Use of non-logged cost variables resulted in non-normal and heteroskedastic residuals. Log-transformation resulted in a more homoskedastic and normal distribution of residuals. Additionally, logging the cost variables allows the interpretation of the coefficients as a percent (%) increase or decrease of differential costs, rather than an absolute dollar amount, which is more relevant to these analyses. Cost variables were also rescaled to 1/1000 (in USD) for ease of interpretation in regression results. For the two individuals who have a [differential costs] value of $0, I set their differential costs equal to $1 so that I could successfully log-transform this variable. $1 was chosen rather than a smaller increment, such as $0.01, to be consistent with all other cost estimates; the smallest unit to which costs could be estimated using the PDPF tool was to the nearest $1.

Residual plots were also used to diagnose whether observations or combinations of independent variables were outliers and therefore causing a model to poorly fit the data. Particularly in a small sample, poorly fit observations contradict the main data pattern and therefore pull model estimates in a contradictory direction.[120] As appropriate, outlier observations were omitted from some

regression models. This approach was used judiciously, and final analytic sample sizes are reported in regression results tables.

Post-estimation model testing: I used post-estimation diagnostic statistics to examine model fit and assumptions. In linear models, I tested model assumptions including: linearity of variable relationships; homoskedasticity; and normality of the error term distribution. I conducted White's test to examine models for heteroskedasticity. Where detected, Huber/White estimators of variance and robust standard errors were reported. I plotted the residuals versus predicted values to determine whether the error term was normally-distributed. Multicollinearity was assessed in linear models by examining the variance inflation factors (VIF) and pairwise correlations.

Interpretation of regression coefficients: In cases of logged dependent variables, I needed to transform the coefficients in order to interpret them. Based upon the above post-estimation test results, all of my results fit the assumptions of a normally-distributed error term and homoskedasticity. To interpret the effect of a dummy variable on the log-transformed dependent variable, I used the following equation:

$$\%\Delta y = 100\left[exp\left(\widehat{\beta_J}\right) - 1\right]$$

While the Kennedy transformation can also be used in cases of normally-distributed error terms and homoskedasticity, I primarly report results from the above equation as it provides almost identical results for small standard errors. In the case of higher standard errors (>0.2), results were compared to Kennedy-transformed results to ensure similarity. Unless significantly different, results using the above transformation are presented, as is more commonly accepted in the literature.

Logistic regression coefficients are interpreted as odds ratios, and are reported in tables both as coefficients and as odds ratios.

All statistical analyses were performed using Stata® 11 (StataCorp LP, College Station TX).

Statistical considerations by specific aim

Aim 1: To describe the distributions of beneficiaries being in lowest-cost plans and differential costs; and whether dual eligible status affects the probability of being enrolled in a lowest-cost plan.

Hypothesis: Dual eligibles will have a lower likelihood of being in lowest-cost plans than non-dual eligibles.

Bivariate Analyses: I operationalized my dependent variable in two ways: lowest-cost plan enrollment and differential costs, as defined above. For the former, I performed a chi-square test comparing duals and non-duals. For the latter, I first conducted a paired t-test. However, because this continuous measure is not normally distributed, I also report results from a Wilcoxon rank-sum (Mann-Whitney *U*) test, a non-parametric approach.

I calculate the prevalence of being in a lowest-cost plan at multiple thresholds, that is, whether the participant is in a plan that is within 10%, 15%, or 20% of the cost of a lowest-cost plan. This is necessary because it is possible that some plans may not be lowest-cost by a nominal amount, in some cases even due to participant choice (about desired plan features that may incur a higher cost). However, a percentage threshold around this estimate allows for appropriate flexibility while still capturing the essence of the lowest-cost plan variable. I estimated descriptive statistics and regression models using costs within these three different percentage cushions around the lowest-cost plan and compared results. Ultimately, however, the final results presented will use this variable to indicate that a beneficiary is in a plan with costs within 10% of the annual out-of-pocket costs in a lowest-cost plan.

Multivariate Analyses: Using multivariate regression, my primary analyses examine the dichotomous variable of whether a participant is in a lowest-cost plan based upon Medicaid status.

$$[Lowest\ cost\ plan\ enrollment]_i = M\left(\alpha_0[Medicaid]_i + \alpha_{1\ldots n}[Z]_{1\ldots n,i}\right) + \varepsilon_1$$

Where *M* is a logit function and;

[Z] is a vector of covariates including: age; near poor; male; race; married; clinic affiliation; plan type; comorbidities; medication expense; informed choice; insurance agent

Secondarily, I examined this hypothesis using [differential costs], rather than [lowest-cost plan enrollment] as the outcome variable of interest. The null hypothesis is that duals have lower differential costs that non-duals.

$$[Differential\ costs]_i = \alpha_0[Medicaid]_i + \alpha_{1\ldots n}[Z]_{1\ldots n,i} + \varepsilon_1$$

[Z] is a vector of covariates including: age; near poor; male; race; married; clinic affiliation; plan type; comorbidities; medication expense; informed choice; insurance agent

Aim 2. To determine the association between lowest-cost plan enrollment/differential costs and CRN, as well as between CRN and clinical outcomes and health services utilization.

Hypotheses:

2a. Beneficiaries in lowest-cost plans will have a lower likelihood of experiencing CRN than those not in lowest-cost plans.

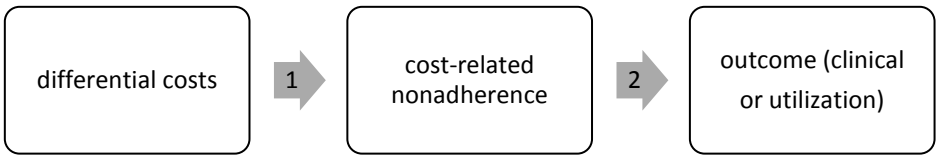
2b. Beneficiaries with lower differential costs will have a lower likelihood of experiencing CRN than those with higher differential costs.

2c. Beneficiaries who experienced CRN will have worse clinical outcomes related to their diabetes than those who did not experience CRN.

2d. Beneficiaries who experienced CRN will have higher health services utilization than those who did not experience CRN.

The pathway that I am trying to estimate is:

Figure 8: Analysis pathway (Aim 2)



There are two ways to conceptualize this aim and the relationship between the variables: (1) consider both equations together using a two-stage instrumental variables (IV) approach and (2) estimate the equations separately without using an IV approach. I attempted both strategies. The primary advantage of the IV approach is the ability to account for potential endogeneity when estimating the relationship between [CRN] and [clinical outcome]. However, this requires identifying a valid instrument, which presents a challenge given the limited number of variables in my dataset. I tested the strength of multiple potential instruments, as discussed below. The latter approach may be

more intuitive in its interpretation (particularly for a clinically-minded audience); however, without controlling for potential endogeneity, the parameter estimates run the risk of being biased.

IV approach

Using the IV approach, we approach this pathway (Figure 8) as one 'causal' chain. By doing so, we need to acknowledge the potentially endogenous [CRN] variable and correct for it; otherwise, we could not estimate the true effect of [differential costs] on [outcome]. In the IV approach, [differential costs], [plan type], and [benefit type detail] act as the instruments because they theoretically only impact patient outcome (clinical or utilization) via their impact on CRN. Plan type and benefit type detail can also act as instruments because they are excluded from the second-stage. It is possible that PDPs may have a different cost structure as compared to MA-PDs and that generosity levels may vary to affect CRN, but not [outcome] directly. In the first-stage equation, I will examine whether the IVs have sufficient explanatory power and variation to be used in place of the potentially endogenous [CRN] variable.

In the IV approach, there are two criteria for a good instrument:

(1) instruments [differential costs, plan type, benefit type detail] are correlated with [CRN]; and

(2) instruments are only correlated with [outcome] via their impact on [CRN].

Specification tests will be used to determine whether these conditions were met, to determine the feasibility of the IV approach. When not large enough, predicted measure will be noisy. In the first-stage equation, I will examine whether the instruments had sufficient explanatory power and variation to be used in place of the potentially endogenous [CRN] variable. This will be done by evaluating the joint F-statistic (or χ^2 for a non-linear function) on the instruments—which conventionally should F-statistic have at least a magnitude of 10—and the R^2/pseudo-R^2 of the regression—which conventionally should have a magnitude of at least 0.2 to 0.3.

If the results of these specification tests suggests that the IV approach is not feasible, my primary analysis will focus on the separate estimation the relationship between [differential costs] and [CRN]; and between [CRN] and [outcome].

Non-IV Approach

If we fail to identify a valid instrument(s), the models will be estimated separately. Differential costs will then be considered exogenous; this seems appropriate, as they are only the

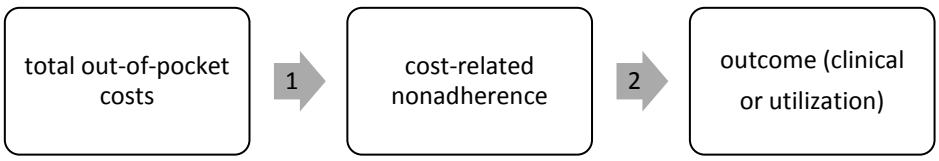
excess costs paid for medications and are not indicative of medication expense itself (which could be jointly determined with outcome). In addition, we were interested in the coefficient estimate on [differential costs] due to its policy significance. We would then minimize endogeneity by including all available and appropriate covariates (defined by the conceptual model).

There may be insufficient statistical power to examine clinical outcomes using multivariate regression, depending upon the number of participants who have clinical lab value in both the pre and post periods. If many have missing values in either one of these periods, they will fall out of regression analyses when the difference is used as the dependent variable. However, I also use the single-item self-rated health status question as a general outcome measure, which will likely have more observations and may therefore be more able to detect a relationship than a clinical lab value specific to one disease.

For the clinical lab values used in aim (2c), I will perform paired t-tests to explore any potential relationships between [CRN] and [outcome]. These results can suggest whether an association may be present, but that may be undetectable using regression analyses. Each model will be run twice: once with [differential costs]$_{\text{"as written"}}$ and once with [differential costs]$_{\text{"generic"}}$.

Aim 3: To determine the association between total out-of-pocket costs and CRN, as well as between CRN and clinical outcomes and health services utilization.

Figure 9: Analysis pathway (Aim 3)



Hypotheses:

3a. Beneficiaries with lower total out-of-pocket costs will have a lower likelihood of experiencing CRN than those with higher total out-of-pocket costs.

3b. Beneficiaries who experienced CRN will have worse clinical outcomes related to their diabetes than those who did not experience CRN.

3c. Beneficiaries who experienced CRN will have higher health services utilization than those who did not experience CRN.

The analytic approach for aim 3 mirrors that of aim 2, but with total out-of-pocket costs, rather than differential costs, as the key independent variable in the first-stage equation. Hypotheses (3b) and (3c) are the same hypotheses (2c) and (2d). I again explored an IV approach, both with and without the addition of [benefit type detail] and [plan type] as the instruments (in addition to [total out-of-pocket costs]). The same specification tests will be used as in aim (2), and if the results of these specification tests suggests that the IV approach is not feasible, my primary analysis will focus on estimating the models separately.

Aim 4: To determine the association between switching plans and differential costs, plan satisfaction, and CRN.

Aim 4 estimates the relationship between previously switching plans and current plan attributes. In the survey, we asked about *previous* plan switching and *current* plan satisfaction, so the hypotheses reflect this time order. The statistical approach includes estimating OLS and logistic regression models, depending upon how the dependent variable is operationalized. Given that all variables are collected from survey data and/or participant characteristics, all analyses are cross-sectional.

Hypotheses:

4a. Beneficiaries who switched plans will have lower differential costs (and will have a higher likelihood of being in a lowest-cost plan) than those who did not switch plans.

$$[Differential\ costs]_i = \alpha_0[Previously\ switched\ plans]_i + \alpha_{1\ldots n}[Z]_{1\ldots n,i} + \varepsilon_1$$

[Z] includes: age; male; race; Medicaid; near poor; married; clinic affiliation; plan type; comorbidities; medication expense; informed choice; insurance agent

Differential costs were log-transformed given their non-normal distribution, and models were estimated for "as written" and generic differential costs. The continuous [differential costs] variable

was replaced with the dichotomous [lowest-cost plan enrollment] variable for a secondary analysis, and a logit function was estimated.

4b. Beneficiaries who switched plans will have a higher likelihood of being satisfied with their current plan than those who did not switch plans.

$$[Plan\ satisfaction]_i = M\left(\alpha_0[Previously\ switched\ plans]_i + \alpha_{1\ldots n}[Z]_{1\ldots n,i}\right) + \varepsilon_1$$

Where *M* is a logit function and;

[Z] is a vector of covariates including: age; male; race; Medicaid; near poor; married; clinic affiliation; plan type; comorbidities; medication expense; informed choice; insurance agent

4c. Beneficiaries who switched plans will have a lower likelihood of experiencing CRN than those who did not switch plans.

$$[CRN]_i = M\left(\alpha_0[Previously\ switched\ plans]_i + \alpha_{1\ldots n}[Z]_{1\ldots n,i}\right) + \varepsilon_1$$

Where *M* is a logit function and;

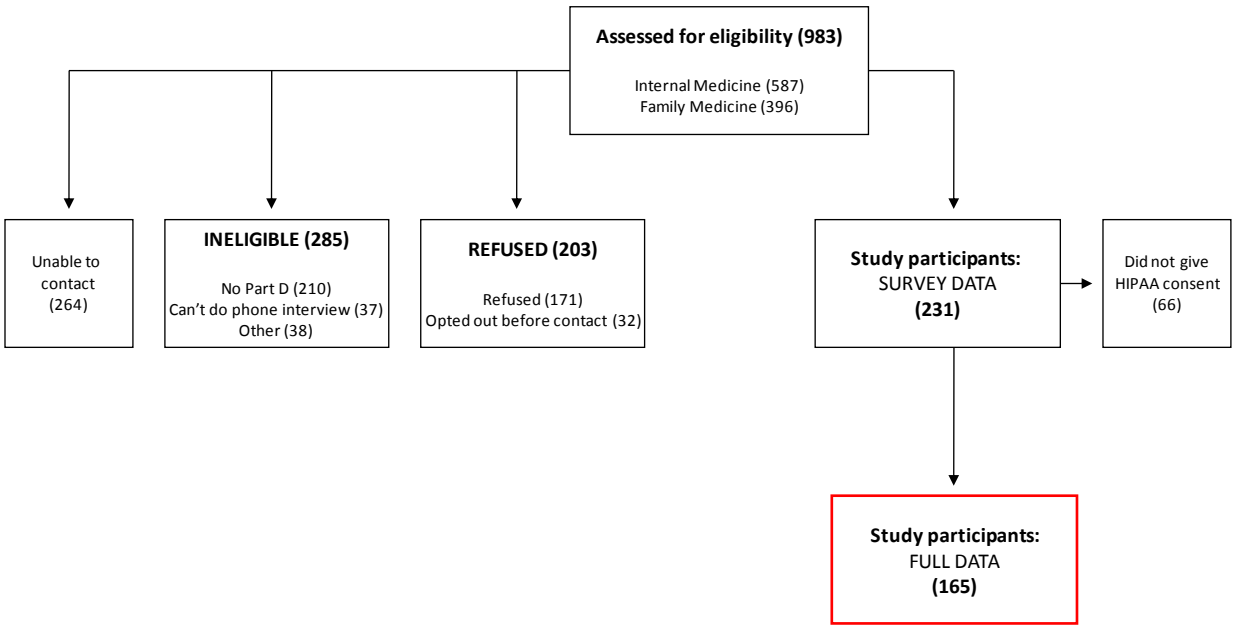
[Z] is a vector of covariates including: age; male; race; Medicaid; near poor; married; clinic affiliation; plan type; comorbidities; medication expense; informed choice; insurance agent

CHAPTER 4: RESULTS

Study participants

We identified 983 individuals in the General Internal Medicine and Family Medicine diabetes registries who were 65 years or older. We made 3,417 phone calls to these potential participants to assess their eligibility and willingness to participate. We were unable to contact 284 persons, 285 were ineligible, and 203 declined to participate (Figure 10). The remaining 231 completed the telephone survey; 66 participants failed to return signed HIPAA consent after multiple contacts. Because these forms were required to access their medical record, the full sample size reduced to 165.

Figure 10: Recruitment



Characteristics of the participants are provided in Table 2. Demographically, the sample was predominately female (61.9%), white (53.0%), and married (57.3%), with a mean age of 73.4 years old. Almost half the sample were enrolled in Medicare Advantage plans (45.1%). Nearly 20% of the sample were dually-eligible for Medicare and Medicaid, and an additional 30.9% were classified as

near poor (incomes between 100-250% FPL). The sample is sicker than the average elderly population. Over half of respondents report that they are in fair or poor health (53.2%). Participants were prescribed an average of 9.2 Part D medications (maximum of 21 prescriptions). The average total out-of-pocket costs (in a beneficiary's current plan) were substantial: $4417 ± 2804 ("as written") and $3042 ± 2206 ("generic").

The most prevalent comorbidities include: chronic obstructive pulmonary disease (30.1%), congestive heart failure (25.9%), and depression (18.1%). Despite their poor self-reported health and number of medications, clinical characteristics suggest that the study sample is well-managed: mean HbA1c = 7.0%, with only 17.2% having an average HbA1c value > 8.0%. The mean systolic and diastolic blood pressures were 138.0 mmHg and 70.7 mmHg, respectively. The mean total and LDL cholesterol were 174.8 and 88.1, respectively. Participants used health services extensively: a mean of 20.9 UNC outpatient clinic visits (range of 1 to 124) and 33.3% of the sample had an inpatient stay during the 12-month study window. Four study participants died during the study period.

Table 2: Study sample characteristics

Study Sample Characteristics			
Demographics	**%**		
Age (mean ± SD)[2]	73.5 (± 5.6)		
Male[1]	38.1		
Nonwhite[2]	47.0		
Medicaid[1]	18.2		
Near poor (100-250% FPL)[2]	30.9		
Married[2]	56.6		
From Family Medicine[1]	30.3		
In Medicare Advantage plan[2]	45.1		
Charlson index (mean ± SD)[2]	1.2 (± 0.9)		
Survey data[1]	**%**		
Experienced cost-related nonadherence	32.9		
Informed plan enrollment choice	38.7		
Insurance agent enrollment assistance	17.0		
Satisfied with plan	73.0		
Switched plans (past year)	23.0		
Has extra help (low-income subsidy)	8.2		
Healthy (excellent, very good, good)	46.8		
Receives immunizations	90.8		
Utilization data[2]	**Median**	**Mean**	**SD**
Had an inpatient stay (1 year)	33.3%		
Outpatient visits (1 year)	17.0	20.9	17.1
Clinical data[2]	**Median**	**Mean**	**SD**
Prescribed number of medications	9.0	9.2	3.5
HbA1c	6.7	7.0	1.0
Blood pressure			
Systolic	136.0	138	15.5
Diastolic	70.7	70.7	8.5
Lipids			
Total cholesterol	166.0	174.8	44.6
Triglycerides	123.0	143.2	82.6
HDL	50.0	52.2	16.5
LDL	82.3	88.1	31.3
Prevalence of select comorbidities	**%**		
Diabetes with chronic complications	45.8		
COPD	30.1		
Congestive heart failure	25.9		
Depression	18.1		
Peripheral vascular disease	13.3		
Myocardial infarction	10.8		

1= Obtained from survey data (n=231)

2= Obtained from medical record data (n=165)

Approximately 1/3 of the sample experienced self-reported cost-related nonadherence (32.9%), which is higher than other published prevalence estimates among Part D beneficiaries.[14, 86] The vast majority of participants were satisfied with their current Part D plan (73.0%), and 23.0% had switched plans in the past year, which is higher than published rates.[14] Additionally, over 90% of respondents answered that they do receive immunizations and vaccines. Given the small degree of variation and that it was only collected for a proportion of the sample, it will not be used as a measure of risk aversion in regression analyses. Participants' responses to an open-ended question about how they chose a plan upon enrollment are presented in Table 3. Half of the sample had some assistance in choosing a part D plan: 32.3% has help from a physician, pharmacist, family member, or friend. The other 17.5% had assistance from an insurance agent, while only 3.9% used Medicare resources to assist them with enrollment.

Table 3: When you first enrolled into Medicare Part D, how did you choose a plan?

	%	n
Used Medicare resources	3.9%	9
Systematic, non-specific strategy	11.3%	26
Had help- from agent	17.0%	39
Had help- not from agent	23.5%	54
Random selection	6.5%	15
Plan loyalty/Brand recognition	9.6%	22
Chose same plan as spouse	1.7%	4
Auto-enrolled	11.7%	27
Don't know/don't remember	14.8%	34
	100.0%	230

Standardizing cost estimates to 2009

Data on out-of-pockets costs spanned parts of three years. Because benefits within plans may change each year and some of the plans available may change each year, we needed to standardize cost estimates across time. I standardized cost estimates empirically. Specifically, I conducted a separate study of 33 participants in the SeniorPharmAssist program, a program to assist seniors who require help with medications. Half of the sample had the low-income subsidy (at varying levels from 25% to 100%), while the other half did not. Using this information, I entered the same prescription medications in the CMS plan finder tool in 2008 an 2009. The median increase between 2008 an 2009 was $768 (29.13%) for those with LIS an $401 (66.79%) for those with LIS. Thus, out-of-pocket costs in 2008 were inflated by these percents. Because there were no data available to conduct

separate analyses for 2010 data, I used the same adjustment factor to standardize costs to 2009 for the 4 participants with data in 2010. The LIS results may be a slight overestimate because there were some LIS individuals for whom the plan choices were outside the set of NC plans that were at/below benchmark status. Therefore, the cost to stay in the plan (that lost benchmark status) would be much greater than the costs if they switched to a new (LIS-approved) plan. There were two companies for which their cost data were not in the PDPF tool. For participants having these two plans (n=8), I manually calculated actual cost estimates using their formularies and plan benefit details (available from company websites). Lowest-cost plan estimates were still available in the PDPF tool in the same manner in which they were calculated for all other participants.

As described in the methods section, we planned a priori to examine differences by site of care (Family Medicine vs. Internal medicine), and whether or not participants returned HIPAA forms. In both comparisons, groups were similar regarding demographic characteristics, site of care, CRN, self-rated health status, plan switching and using help to choose a plan (results not shown).

Results by specific aim

Aim 1.

To describe the distributions of beneficiaries being in lowest-cost plans and differential costs; and whether dual eligible status affects the probability of being enrolled in a lowest-cost plan.

Regardless of assumptions about generic substitutions, only one-quarter of the sample is enrolled in a lowest-cost plan, defined as having out-of-pocket costs within 10% of a lowest-cost plan. Specifically, assuming prescriptions are filled as written, 25.5% of the sample is in a lowest-cost plan. Assuming generic substitutions, 24.9% of the sample is in a lowest-cost plan. Analyses around the 10% estimate indicate that this is an appropriate cut-off level. Sensitivity analyses found that using 15% or 20% as the threshold makes very little difference in the estimate (

Table 4). Regression results did not significantly change when the 15% or 20% thresholds were used instead.

Table 4: Various estimates for lowest-cost plan enrollment

% threshold around estimate	Substitution assumption	% of sample in lowest-cost plan
0	"as written"	4.2
	"generic"	6.1
10	"as written"	25.5
	"generic"	24.9
15	"as written"	33.3
	"generic"	36.4
20	"as written"	39.4
	"generic"	40.6

Not only are most patients not in a lowest-cost plan, but the additional amount they would have to pay out-of-pocket is substantial. On average, participants are paying 30% more than necessary to obtain medications. The median differential costs suggest that more than half of participants are in plans that requires out-of-pocket costs at least $715 (“as written”) / $489 (“generic”) more than the lowest-cost plan (Table 5). Moreover, the person with the highest differential cost would pay $7729 (“as written”) or $7288 (“generic”) more than in a lowest-cost plan.

Table 5: Descriptive cost data

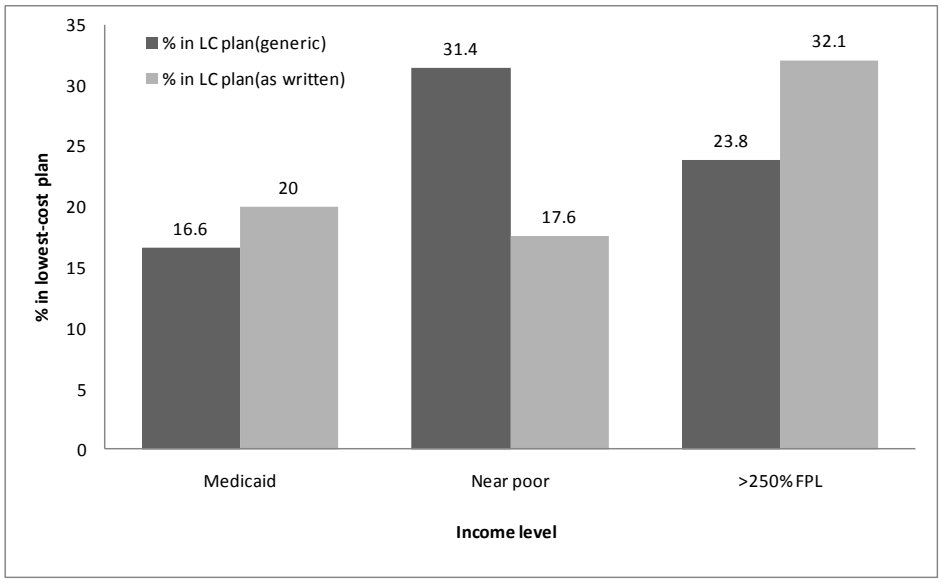
Cost data (n=165)	%		
In lowest-cost plan ("as written")	4.2		
In lowest-cost plan ("generic")	6.1		
Within 10% of LC plan ("as written")	25.5		
Within 10% of LC plan ("generic")	24.9		
Within 15% of LC plan ("as written")	33.3		
Within 15% of LC plan ("generic")	36.4		
Within 20% of LC plan ("as written")	39.4		
Within 20% of LC plan ("generic")	40.6		
	Median	**Mean**	**SD**
Differential costs ("as written")	$715	$1,215	$1,567
Differential costs ("generic")	$489	$692	$875
Total out-of-pocket costs ("as written")	$4,535	$4,417	$2,804
Total out-of-pocket costs ("generic")	$2,888	$3,042	$2,206

-

Primary hypothesis (lowest-cost plan enrollment)*:* Dual eligibles will have a lower likelihood of being in lowest-cost plans than non-dual eligibles.

Bivariate analyses: Dual status was not associated with being in a lowest-cost plan, assuming either "as written" (χ^2=0.57) or "generic" (χ^2=1.31) medications. Thus, this hypothesis was not supported. I also examined the bivariate association between income level and lowest-cost plan enrollment (Figure 11) and found no significant difference in low-cost plan enrollment (p=0.32 ("generic"); p=0.13 ("as written")).

Figure 11: Percent in lowest-cost plan by income level

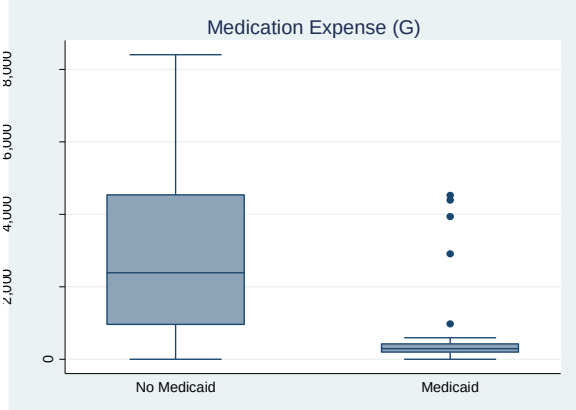


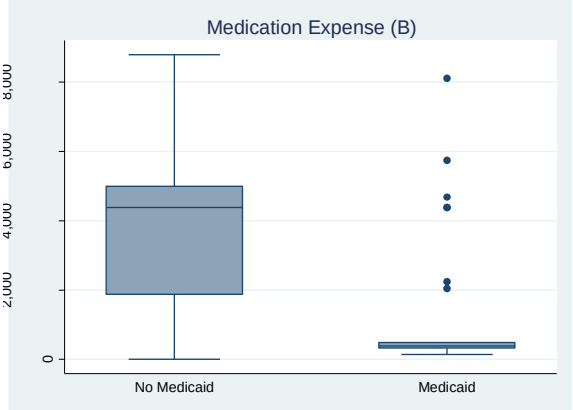
Individuals with Medicaid had a significantly different distribution of medication expenses than those without Medicaid), regardless of whether we considered generic substitutions. The medication expenses were significantly higher overall for those without Medicaid (Figure 12).

Figure 12: Distribution of medication expense by Medicaid status ("generic" & "as written")

Generic	No Medicaid	Medicaid
Median	$2390	$299
Mean	$2700	$776
SD	$1992	$1296

As written	No Medicaid	Medicaid
Median	$4379	$389
Mean	$3624	$1306
SD	$2038	$2033



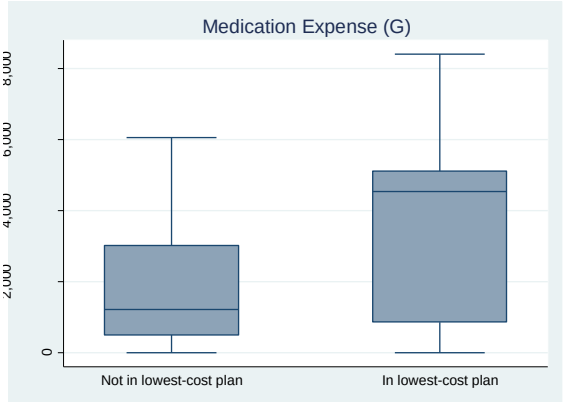


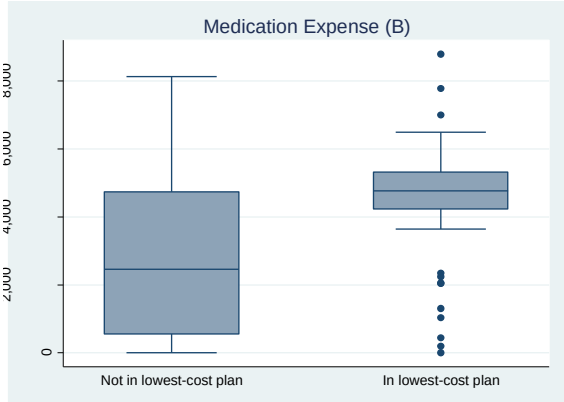
In the multivariate models (both "as written" and "generic"), higher medication expense were associated with a greater likelihood of being in a lowest-cost plan. The direction of the multivariate relationship is in the same direction as the association in the bivariate relationship (Figure 13).

Figure 13: Distribution of medication expense by lowest-cost plan enrollment ("generic" & "as written")

Generic	Not in LC plan	In LC plan
Median	$1217	$4536
Mean	$1879	$3773
SD	$1648	$2381

As written	Not in LC plan	In LC plan
Median	$2457	$4768
Mean	$2796	$4392
SD	$2172	$1933





Multivariate analyses (Table 6): For both "as written" and "generic" costs, there is no significant association between dual status and being in a lowest-cost plan. In the "as written" model only, being near poor is associated with a 68% decrease in the odds of being in a lowest-cost plan (OR=0.32; $p<0.05$). In both the "generic" and "as written" models, higher medication expense is significantly associated with a higher likelihood of being in a lowest-cost plan ($p<0.001$). Holding all else constant, there will be an 161% ("generic")/67% ("as written") increase in the odds of being in of a lowest-cost plan for a $1000 increase in medication expense ($p<0.001$). In the "generic" model only, a one-unit increase in the Charlson index comorbitiy score is associated with a 66% decrease in the odds of being in a lowest-cost plan ($p<0.01$), and a one year increase in age is associated with a 12% decrease in the odds of being in a lowest-cost plan ($p<0.01$).

Table 6: Logistic regression results for Aim 1: The effect of Medicaid on lowest-cost plan enrollment

	"Generic" OR	"Generic" Coeff	"As written" OR	"As written" Coeff
Has Medicaid	1.38 (1.14)	0.32 (0.83)	1.60 (1.14)	0.47 (0.71)
Near poor	0.71 (0.39)	-0.35 (0.55)	**0.32*** **(0.16)**	**-1.13*** **(0.51)**
Age	**0.88**** **(0.04)**	**-0.13**** **(0.05)**	0.98 (0.04)	-0.02 (0.04)
Male	1.64 (0.84)	0.49 (0.51)	1.71 (0.77)	0.54 (0.45)
Nonwhite	2.33 (1.20)	0.85 (0.52)	1.11 (0.50)	0.10 (0.45)
Single	1.02 (0.53)	0.02 (0.52)	0.59 (0.27)	-0.52 (0.45)
In Medicare Advantage	1.06 (0.55)	0.06 (0.52)	1.37 (0.60)	0.31 (0.44)
Charlson index	**0.34**** **(0.12)**	**-1.09**** **(0.37)**	1.02 (0.26)	0.02 (0.26)
Informed choice	0.51 (0.28)	-0.68 (0.56)	0.90 (0.44)	-0.11 (0.49)
Insurance agent	0.26+ (0.21)	-1.34+ (0.79)	1.32 (0.77)	0.28 (0.58)
Family Med Clinic	0.31+ (0.19)	-1.17+ (0.60)	1.27 (0.57)	0.24 (0.45)
Medication expense (Generic)	**2.61***** **(0.50)**	**0.96***** **(0.19)**		
Medication expense (As written)			**1.67***** **(0.19)**	**0.51***** **(0.12)**
Constant	806.34+ (2916.49)	6.69+ (3.62)	0.18 (0.53)	-1.70 (2.90)
Observations	160	160	163	163
Pseudo R^2	0.336	0.336	0.182	0.182

Standard errors in parentheses
+ $p < 0.10$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

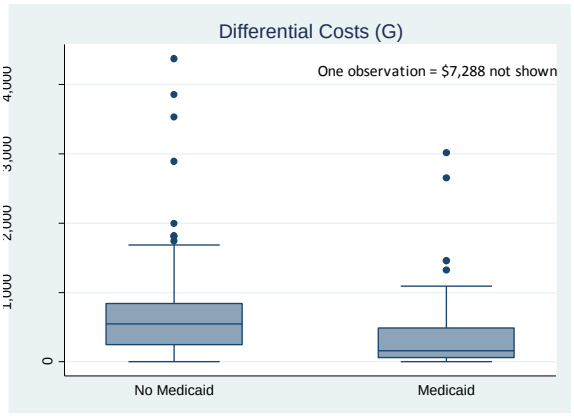
Secondary hypothesis (differential costs): Dual eligibles will have lower differential costs than non-dual eligibles.

Bivariate analyses: In the Wilcoxon rank-sum test analyses, the distributions of differential costs are different for duals and non-duals (Figure 14). This difference was statistically significant for "generic" and "as written" medication costs ("generic:" z=2.46; p<0.01; "as written:" z=-1.95; p<0.10). Of note, the difference was in opposite directions: for "as written" costs, having Medicaid is associated with *higher* differential costs, whereas for "generic" costs, having Medicaid is associated with *lower* differential costs (Figure 14). ANOVA results indicate that "as written" differential costs decrease with increasing income levels (F=6.03; p<0.01). And, "as written" differential costs are higher than "generic" differential costs across income categories, as expected (Figure 15).

Figure 14: Distribution of differential costs expense by Medicaid status ("generic" & "as written")

Generic	No Medicaid	Medicaid
Median	$545	$165
Mean	$686	$718
SD	$696	$1447

As written	No Medicaid	Medicaid
Median	$696	$1206
Mean	$1074	$1849
SD	$1429	$1986



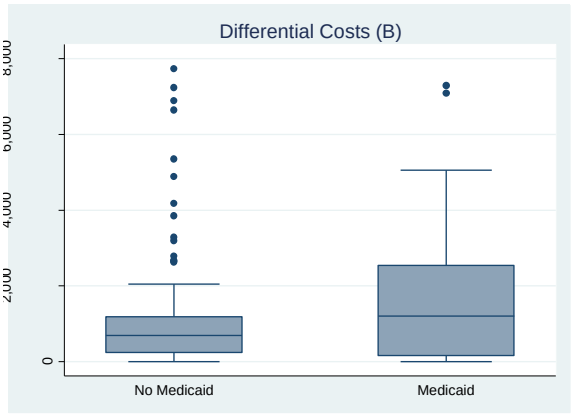
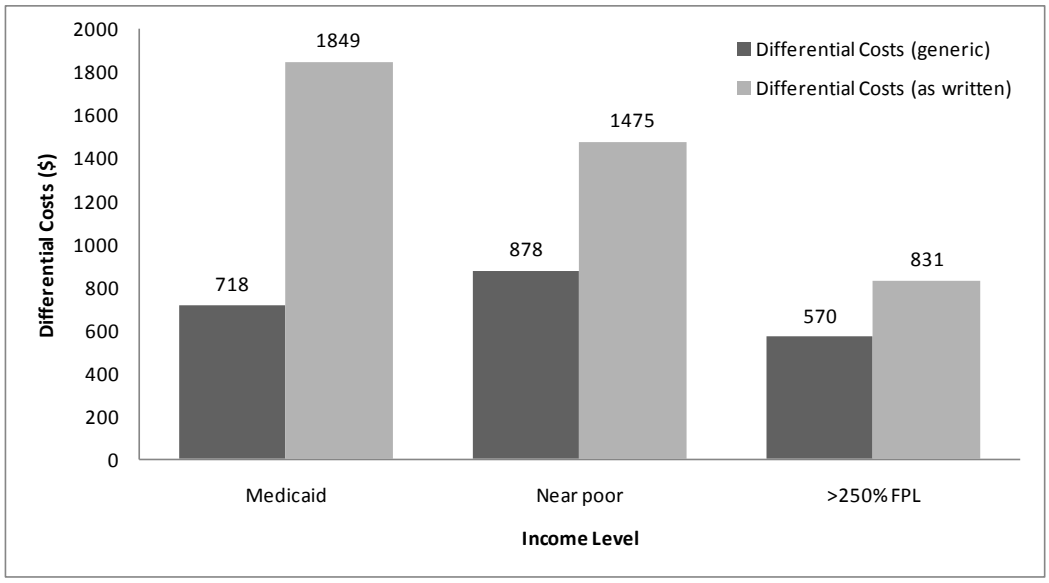


Figure 15: Differential costs by income level



Multivariate analyses (Table 7): This model was run only for people who had any differential costs. That is, I omitted the 7 ("as written")/12 ("generic") participants with differential costs < $10/year because they were poorly fit by the linear model and identified as outliers on the residuals plot. In the "as written" model only, having Medicaid was associated with an 84.1% increase in differential costs ($p<0.10$). The Kennedy transformation was used to interpret this coefficient, because the standard error is above 0.2 (0.36).

In both models, being near poor is significantly associated with a 49.5% ($p<0.05$) and 95.6% ($p<0.01$) increase in differential costs for "generic" and "as written" costs, respectively. Being in a Medicare Advantage plan, rather than a PDP, is also associated with a 27.2% ($p<0.10$) and 50.2% ($p<0.01$) decrease in differential costs, respectively, for "generic" and "as written" medications. Lastly, in the "generic" model only, being from Family Medicine is associated with a 68.3% increase in differential costs relative to being from General Internal Medicine ($p<0.01$).

Table 7: OLS regression results for Aim 1: The effect of Medicaid on differential costs

	"Generic" Coeff	"As written" Coeff
Has Medicaid	-0.23 (0.27)	0.67+ (0.36)
Near poor	**0.40*** **(0.20)**	**0.70**** **(0.25)**
Age	0.02 (0.02)	0.00 (0.02)
Male	-0.22 (0.18)	-0.31 (0.23)
Nonwhite	-0.15 (0.18)	-0.29 (0.22)
Single	-0.26 (0.19)	0.18 (0.23)
In Medicare Advantage	-0.32+ (0.19)	**-0.70**** **(0.22)**
Charlson index	0.00 (0.11)	-0.10 (0.13)
Informed choice	0.24 (0.19)	0.24 (0.24)
Insurance agent	-0.08 (0.27)	-0.27 (0.32)
Family Med Clinic	**0.52**** **(0.19)**	0.16 (0.24)
Log medication expense (Generic)	0.01 (0.05)	
Log medication expense (As written)		-0.06 (0.11)
Constant	-2.39* (1.19)	-0.36 (1.46)
Observations	151	155
R^2	0.177	0.222

Standard errors in parentheses
+ $p < 0.10$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Aim 2.

To determine the association between lowest-cost plan enrollment/differential costs and CRN, as well as between CRN and clinical outcomes and health services utilization.

Model specifications: *In all model specifications, the potential instruments failed.* [Differential costs] (both "as written" and "generic") and [plan type] were tried as instruments, both with and without the addition of [benefit type detail]. In each case, the test for joint significance of these potential instruments was not significant. The χ^2 test statistics are 2.23 ("as written") and 2.57 ("generic") when benefit type is not used. The χ^2 test statistics are 2.25 ("as written") and 3.65 ("generic") when benefit type is added as a potential instrument. None of these test statistics are greater than the conventionally-accepted magnitude of 10 and do not reach significance at the conventional α=0.05 level.

The pseudo-R^2 values for these four models ranged from 0.09 to 0.1. These values are less than the 0.2-0.3 that is generally accepted as high enough to proceed with a two-stage approach.[121] According to Bollen et al. (1995), The R^2 should be at least 0.1 with a large sample, since the actual measure of CRN would be replaced with the predicted value from the first-step equation.[122] If the R^2/pseudo-R^2 isn't large enough, this predicted measure will be noisy. My relatively-small sample is also a consideration in determining whether an IV approach is biased back towards estimating the simple model.

[Differential costs], [plan type], and [benefit type detail]) do not have good predictive power. If the first stage does not have good predictive power, those predicted values of [CRN] will become a poor proxy in the second stage.[122] This holds whether we use the predicted values of [CRN] in the second stage (2SLS) or add the residuals derived from predicted [CRN] values to the second stage (2SRI).[123] Because I lacked good instruments, it is unnecessary to perform additional specification tests with the second stage equation (e.g., Hausman test to determine whether additional instruments are validly excluded from the main equation; t-test on the 1st stage error term to test exogeneity of [CRN]).

Even if endogeneity is a problem, the two-step estimation method may not be preferable for three reasons: (1) the R^2 of the first-stage equation is low; (2) the sample size is small; and (3) the degree of identification is low.[122]

My pseudo-R^2 values are not above the generally-accepted 0.2-0.3 level that is preferable when the two steps do not have a high degree of identification.

My sample sizes for the equations using clinical data range from 20 to 111, which is generally considered too small of a sample for use in an IV approach.

There is not a high degree of identification, given that most of the covariates overlap and are used in both the first and second stage equations. According to Bollen et al. (1995), if the variable overlap is 75% or more (which it is in the instance, with only 2-3 variables unique to the first stage), the IV approach almost always fails and it is more appropriate to estimate the simple model.[122]

When the potential instruments are weakly correlated with CRN, the IV approach is not desirable even if the sample is large.[124] Given that I have invalid instruments, the two-stage results would be biased towards estimating the simple models. Therefore, it is more appropriate to estimate the structural equation of the relationship between CRN and outcome (Eq. 2) and hypothesize the direction of any potential biases related to omitted variables. Given the limitations of my available potential instruments, I use a non-IV approach as set forth in the Methods section to estimate Aim 2.

Hypotheses:

Aim 2a: Beneficiaries in lowest-cost plans will have a lower likelihood of experiencing CRN than those not in lowest-cost plans.

Bivariate analyses: For both "generic" and "as written" medication costs, there is a significant bivariate association between being in a lowest-cost plan and experiencing CRN for both "generic" (χ^2=7.85; p<0.01) and "as written" (χ^2=3.59; p=0.06) medications. However, this relationship is in the unexpected direction: beneficiaries in lowest-cost plans are more likely to experience CRN. We explored medication expense as one potential explanation for this unexpected relationship, and did not find that the prevalence of CRN relative to being in a lowest-cost plan differed significantly across quartiles of medication expense for either "generic" (Figure 16) or "as written" (Figure 17) costs.

Figure 16: Percentage with CRN by quartiles of medication expense ("generic")

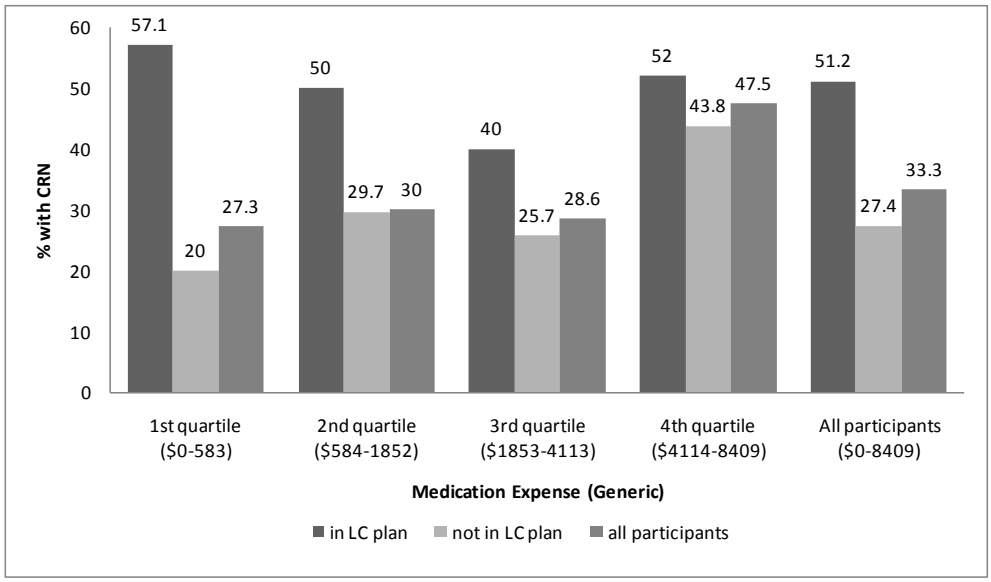
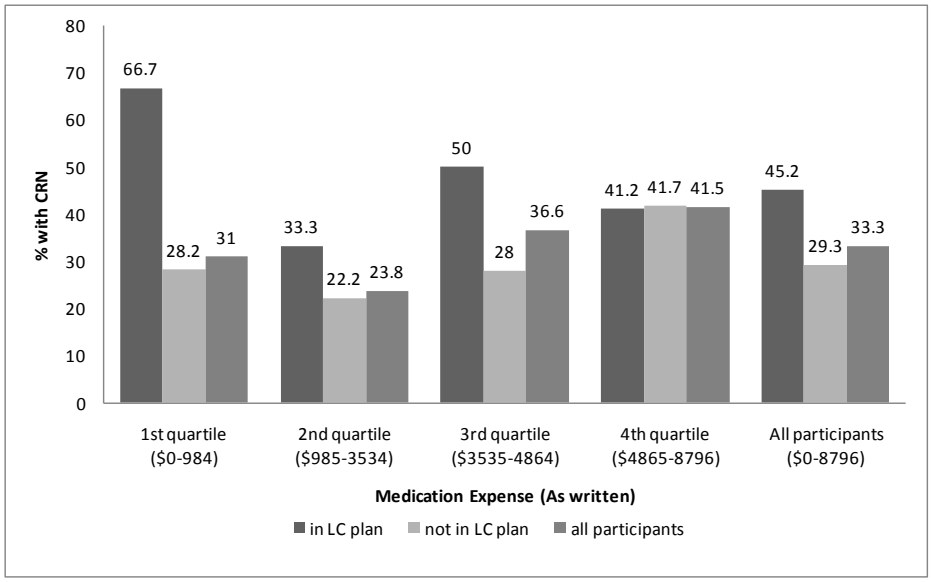
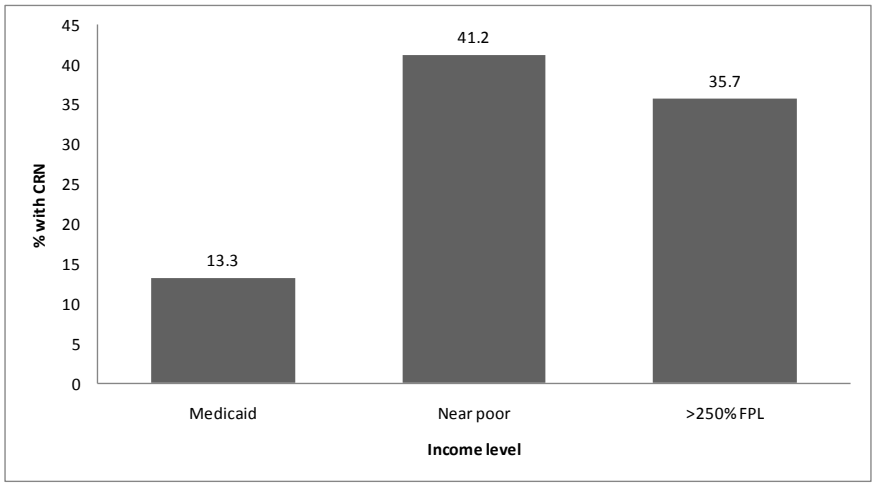


Figure 17: Percentage with CRN by quartiles of medication expense ("as written")



I also examined the prevalence of CRN as a function of income category, and while it appears as if those near poor (middle income category experience higher rates of CRN, this difference is not significant (Figure 18). An ANOVA test determined that there was no significant difference of the prevalence of CRN across income categories.

Figure 18: Percentage with CRN by income level



Multivariate analyses: In both logistic regression models, being in a lowest-cost plan is associated with a higher likelihood of experiencing CRN. In the "generic" model, holding all else constant, there will be a 265% increase in the odds of experiencing CRN if a beneficiary is in a lowest-cost plan (OR=3.65; $p<0.01$). In the "as written" model, the relationship approaches significance at $\alpha=0.10$ with an odds ratio of 2.15. This relationship is in an unexpected direction.

In the "as written" model only, I observed an 83% decrease in the odds of experiencing CRN for beneficiaries who have Medicaid, relative to those who do not ($p<0.05$). Having help from an agent also approaches significance only in the "generic" model, which is associated with a 146% increase in the odds of experiencing CRN (OR=2.46; $p<0.15$) (Table 8).

Table 8: Logistic regression results for Aim 2a: The effect of lowest-cost plan enrollment on CRN

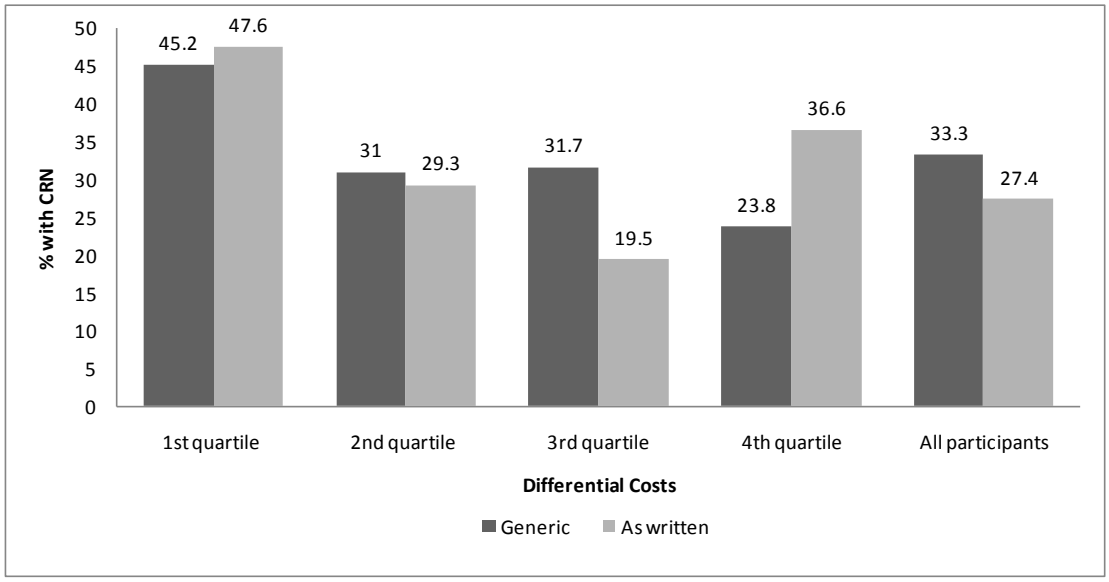
	"Generic" OR	"Generic" Coeff	"As written" OR	"As written" Coeff
In low-cost plan (Generic)	**3.65** (1.73)**	**1.30** (0.47)**		
In low-cost plan (As written)			2.15+ (0.96)	0.76+ (0.45)
Has Medicaid	0.36 (0.24)	-1.03 (0.68)	**0.17* (0.14)**	**-1.79* (0.85)**
Near poor	1.38 (0.59)	0.32 (0.42)	1.36 (0.57)	0.31 (0.42)
Age	0.95 (0.04)	-0.05 (0.04)	0.95 (0.03)	-0.05 (0.04)
Male	0.84 (0.34)	-0.18 (0.40)	0.88 (0.35)	-0.13 (0.40)
Nonwhite	0.93 (0.37)	-0.07 (0.40)	1.05 (0.41)	0.05 (0.39)
Single	0.86 (0.35)	-0.15 (0.40)	0.86 (0.35)	-0.15 (0.40)
In Medicare Advantage	1.42 (0.56)	0.35 (0.40)	1.19 (0.47)	0.17 (0.39)
Charlson index	1.31 (0.31)	0.27 (0.24)	1.14 (0.26)	0.13 (0.23)
Informed choice	0.86 (0.37)	-0.15 (0.43)	0.96 (0.40)	-0.04 (0.42)
Insurance agent	2.46+ (1.30)	0.90+ (0.53)	2.28 (1.20)	0.82 (0.53)
Family Med Clinic	1.22 (0.50)	0.20 (0.41)	0.94 (0.38)	-0.06 (0.40)
Medication expense (Generic)	0.89 (0.11)	-0.11 (0.12)		
Medication expense (As written)			0.96 (0.10)	-0.04 (0.10)
Constant	12.20 (34.39)	2.50 (2.82)	11.31 (31.07)	2.43 (2.75)
Observations	162	162	161	161
Pseudo R^2	0.122	0.122	0.112	0.112

Standard errors in parentheses
+ $p < 0.10$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Aim 2b: Beneficiaries with lower differential costs will have a lower likelihood of experiencing CRN than those with higher differential costs.

Bivariate analyses: When examining differential costs by quartiles and their association with lowest-cost plan enrollment and CRN, we observe that individuals in lowest-cost plans experience higher rates of CRN across the first three quartiles of differential costs (there were no participants in lowest-cost plans in the 4th quartile of differential costs (Figure 19). This may indicate that there is not one particular threshold of spending (as indicated by differential costs) at which beneficiaries are particularly susceptible to CRN.

Figure 19: Percentage with CRN by quartiles of differential costs ("generic" & "as written")



Multivariate analyses: Differential costs are significantly associated with CRN in the "as written" model only. There is a 36% increase in the odds of experiencing CRN associated with a $1000 increase in differential costs ($p<0.05$). The only significant covariate in the "as written" model is Medicaid, which also approaches significance in the "generic" model. Having Medicaid is significantly associated with a 77-90% decrease in the likelihood of experiencing CRN relative to participants who do not have Medicaid (OR=0.10; $p<0.05$ ("as written")/OR=0.23; $p<0.10$ ("generic")). In the "as written" model, participants who had assistance enrolling into their plan from an insurance agent have higher odds of experiencing CRN (OR=2.51; $p<0.10$) (Table 9). There are no additional significant covariates in the "generic" model.

Table 9: Logistic regression results for Aim 2b: The effect of differential costs on CRN

	"Generic" OR	"Generic" Coeff	"As written" OR	"As written" Coeff
Differential costs (Generic)	0.76 (0.23)	-0.27 (0.30)		
Differential costs (As written)			**1.36* (0.18)**	**0.31* (0.13)**
Has Medicaid	0.23+ (0.19)	-1.45+ (0.83)	**0.10* (0.09)**	**-2.30* (0.94)**
Near poor	1.29 (0.56)	0.26 (0.43)	1.07 (0.46)	0.07 (0.42)
Age	0.95 (0.04)	-0.05 (0.04)	0.97 (0.04)	-0.03 (0.04)
Male	0.95 (0.39)	-0.06 (0.41)	0.81 (0.34)	-0.21 (0.42)
Nonwhite	1.18 (0.48)	0.17 (0.40)	1.23 (0.49)	0.20 (0.40)
Single	0.72 (0.30)	-0.32 (0.42)	0.88 (0.37)	-0.12 (0.42)
In Medicare Advantage	1.18 (0.49)	0.17 (0.41)	1.95 (0.82)	0.67 (0.42)
Charlson index	1.35 (0.33)	0.30 (0.24)	1.15 (0.27)	0.14 (0.23)
Informed choice	1.09 (0.47)	0.09 (0.44)	0.99 (0.43)	-0.01 (0.43)
Insurance agent	2.28 (1.25)	0.82 (0.55)	2.51+ (1.37)	0.92+ (0.54)
Family Med Clinic	1.12 (0.48)	0.11 (0.43)	0.87 (0.38)	-0.14 (0.43)
Medication expense (Generic)	1.06 (0.11)	0.05 (0.11)		
Medication expense (As written)			0.99 (0.10)	-0.01 (0.10)
Constant	9.62 (27.15)	2.26 (2.82)	1.97 (5.56)	0.68 (2.82)
Observations	151	151	156	156
Pseudo R^2	0.105	0.105	0.128	0.128

Standard errors in parentheses
+ $p < 0.10$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Aim 2c: Beneficiaries who experienced CRN will have worse clinical outcomes related to their diabetes than those who did not experience CRN.

Self-reported health status (Table 10): CRN is negatively associated with self-reported health status, both in bivariate and multivariate analyses. Experiencing CRN is associated with a 69% decrease in the odds of the participant being in good health (OR=0.31; p<0.01). Additionally, we see a 28% decrease in the odds of being in good health for every $1000 increase in medication expense (OR=0.72; p<0.01). As comorbidity score increases (sicker participants), the likelihood of being in good health decreases (OR=0.64; p,0.05).

Table 10: Logistic regression results for Aim 2c: The effect of CRN on general health status

	OR	Coeff
CRN	**0.31****	**-1.16****
	(0.13)	**(0.41)**
Has Medicaid	1.14	0.13
	(0.63)	(0.56)
Near poor	0.83	-0.18
	(0.38)	(0.45)
Age	0.95	-0.06
	(0.03)	(0.04)
Male	1.39	0.33
	(0.55)	(0.39)
Nonwhite	0.69	-0.38
	(0.27)	(0.39)
Single	1.55	0.44
	(0.63)	(0.41)
Charlson index	**0.64***	**-0.45***
	(0.14)	**(0.23)**
Family Med Clinic	1.50	0.41
	(0.60)	(0.40)
Medication expense (Generic)	**0.72****	**-0.33****
	(0.08)	**(0.11)**
Constant	198.59+	5.29+
	(545.59)	(2.75)
Observations	157	157
Pseudo R^2	0.166	0.166

Standard errors in parentheses
+ $p < 0.10$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

HbA1c (Table 11):In the OLS model, CRN is not significantly associated with HbA1c and there are no significant covariates in the model. Age approaches significance at the $\alpha=0.10$ level, with older age being associated with a slightly lower HbA1c value in the post period. However, the bivariate association between CRN and the difference in HbA1c value between pre and post period approaches significance at the $\alpha=0.10$ level ($t=1.94$; $p=0.06$). However, the relationship is in the unexpected direction: individuals experiencing CRN have lower scores in the post period than the pre period, while individuals without CRN have higher scores in the post period than they did in the pre period.

Blood pressure (Table 11): CRN is associated with a 7.37 unit (SE=4.03) drop in systolic BP from pre to post period ($p<0.10$). Experiencing CRN is significantly associated with a 4.45 unit (SE=1.79) drop in diastolic BP from pre to post period ($p<0.05$). In the systolic model, being male is associated with a 7.78 unit (SE=3.89) increase in BP from pre to post period ($p<0.05$). There are no additional significant covariates in the diastolic model. When examining bivariate associations, there is no significance between CRN and systolic BP, but those who experience CRN are significantly more likely to have lower diastolic BP post values relative to their pre values ($t=2.40$; $p<0.05$).

Lipids (Table 11): Results are only presented for total cholesterol and HDL, as LDL and triglycerides were not collected with enough frequency in both the pre and post periods. The cholesterol and HDL results should also be interpreted with caution, as there are only 20 and 21 observations, respectively. In both models, there is no significant association between CRN and lipid values. In the HDL model, being nonwhite is associated with an 11.03 lower HDL value (SE=4.98) in the post period at the $\alpha=0.10$ level. This is the only association that approaches significance. There are no significant bivariate associations between CRN and either total cholesterol or HDL.

Table 11: OLS regression results for Aim 2c: The effect of CRN on clinical outcomes

	HbA1c	Systolic BP	Diastolic BP	Cholesterol	HDL
CRN	-0.54	-7.37+	**-4.45***	-6.52	0.61
	(0.34)	(4.03)	**(1.79)**	(25.34)	(3.73)
Has Medicaid	-0.15	-5.54	-0.32	25.66	9.84
	(0.53)	(6.38)	(2.83)	(84.29)	(12.40)
Near poor	-0.16	0.28	0.47	-23.63	-1.59
	(0.33)	(4.20)	(1.86)	(28.33)	(4.17)
Age	-0.05	0.02	0.02	1.98	0.13
	(0.03)	(0.33)	(0.15)	(3.36)	(0.49)
Male	-0.13	7.78*	0.04	3.82	-5.02
	(0.32)	(3.89)	(1.73)	(32.09)	(4.65)
Nonwhite	-0.33	4.17	1.27	-37.43	-11.03+
	(0.34)	(4.00)	(1.77)	(34.90)	(4.98)
Single	-0.35	-3.09	-2.79	-15.35	-5.84
	(0.33)	(4.03)	(1.79)	(39.07)	(5.71)
Charlson index	0.16	2.82	1.22	-15.44	-0.72
	(0.18)	(2.37)	(1.05)	(18.49)	(2.34)
Family Med Clinic	-0.28	-2.74	-0.85	-40.91	-2.64
	(0.37)	(4.21)	(1.87)	(32.38)	(4.53)
Log medication expense (Generic)	-0.05	1.01	0.65	9.96	2.26
	(0.11)	(1.18)	(0.52)	(15.03)	(2.07)
Constant	3.87+	-6.10	-0.92	-83.60	-2.49
	(2.09)	(25.52)	(11.32)	(237.54)	(34.99)
Observations	67	111	111	20	21
R^2	0.142	0.130	0.120	0.495	0.588

Standard errors in parentheses
+ $p < 0.10$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Aim 2d: Beneficiaries who experienced CRN will have higher health services utilization than those who did not experience CRN.

Outpatient visits (Table 12): Holding all else constant, participants who experienced CRN had 2.28 (SE=0.84) more outpatient visits to a UNC clinic during the post period than those who did not experience CRN ($p<0.01$). A 1-unit increase in the Charlson index (being sicker) is associated ($\alpha=0.10$) with 0.82 less outpatient visits in the post period relative to the number of visits in the pre period. The bivariate association shows a similar trend: those who experienced CRN had 1.0 more outpatient visits, while those without CRN had 0.95 less visits in the post period relative to the pre period ($t=-2.45$; $p<0.05$).

Inpatient stays (Table 12): 33.3% of patients had a hospitalization at UNC during the course of the study period. In both bivariate and multivariate models, there is a significant association between CRN and inpatient visits. Holding all else constant, participants who experienced CRN had a 259% increase in the odds of having an inpatient stay during the post period relative to beneficiaries who did not experience CRN (OR=3.59; $p<0.05$). The nonwhite and Charlson index covariates were also significant. Nonwhite participants had a 267% increase in the odds of having an inpatient stay (OR=3.67; $p<0.05$) and a 1-unit increase in comorbidity score was associated with a 703% increase in the odds of having an inpatient stay (OR=8.03; $p<0.001$). Having a previous inpatient stay was not predictive of having an inpatient stay in the post period.

Table 12: OLS and logistic regression results for Aim 2d: The effect of CRN on health services utilization

	Outpt (Coeff)	Inpt (OR)	Inpt (Coeff)
CRN	**2.28****	**3.59***	**1.28***
	(0.84)	**(2.13)**	**(0.59)**
Has Medicaid	1.45	0.96	-0.04
	(1.21)	(0.89)	(0.93)
Near poor	-0.40	0.94	-0.07
	(0.93)	(0.63)	(0.68)
Age	0.01	1.01	0.01
	(0.07)	(0.05)	(0.05)
Male	1.33	1.94	0.66
	(0.84)	(1.19)	(0.61)
Nonwhite	-0.63	**3.67***	**1.30***
	(0.83)	**(2.32)**	**(0.63)**
Single	-0.15	2.11	0.75
	(0.85)	(1.28)	(0.61)
Charlson index	-0.82+	**8.03*****	**2.08*****
	(0.48)	**(5.02)**	**(0.62)**
Family Med Clinic	-0.44	1.95	0.67
	(0.87)	(1.20)	(0.62)
Log medication expense (Generic)	0.05		
	(0.22)		
Medication expense (Generic)		0.84	-0.17
		(0.15)	(0.18)
Previous inpatient visit		0.65	-0.43
		(0.57)	(0.88)
Constant	-0.85	0.00+	-7.33+
	(5.55)	(0.00)	(4.14)
Observations	164	163	163
R^2	0.091		
Pseudo R^2		0.256	0.256

Standard errors in parentheses
+ $p < 0.10$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Aim 3.

To determine the association between total out-of-pocket costs and CRN, as well as between CRN and clinical outcomes and health services utilization.

Aim 3 model specification: *In all model specifications, the potential instruments failed.* [Total out-of-pocket costs] (both "as written" and "generic") and [plan type] were tried as instruments, both with and without [benefit type detail]. In each case, the test for joint significance of these potential instruments was not significant. The χ^2 test statistics were 2.76 ("as written") and 3.60 ("generic") when [benefit type detail] is not used. The χ^2 test statistics were 2.75 ("as written") and 4.56 ("generic") when [benefit type detail] was added as a potential instrument. None of these test statistics reached significance at the conventional α=0.05 level. The pseudo-R^2 values for these four models ranged from 0.07 to 0.08. Again, these values are not considered high enough to proceed with a two-stage approach given my sample size. Therefore, [total out-of-pocket costs], [plan type], and [benefit type detail] do not have good predictive power to use as an instrument.

The chosen approach is the same as in aim 2, where I estimated Eqs. 2 and 3 separately. Aims 3b. and 3c. are explored by estimating the same models as described in aims 2b. and 2c. Again, small sample sizes limit the ability to detect an association between [CRN] and [outcome], and exploratory bivariate associations were estimated.

Hypotheses:

Aim 3a: Beneficiaries with lower total out-of-pocket costs will have a lower likelihood of experiencing CRN than those with higher total out-of-pocket costs.

There are no bivariate or multivariate associations between total out-of-pocket costs and CRN for either "as written" or "generic" costs. In the "generic" and "as written" models, the Medicaid variable indicates that participants with Medicaid have 91% ("generic")/ 92% ("as written") lower odds of experiencing CRN relative to those without Medicaid (OR=0.09 ("generic")/ 0.08 ("as written"); $p<0.05$) (Table 13). There are no other significant covariates in the model.

Table 13: Logistic regression results for Aim 3a: The effect of total out-of-pocket costs on CRN

	"Generic" OR	"Generic" Coeff	"As written" OR	"As written" Coeff
Total OOP cost (Generic)	1.02 (0.10)	0.02 (0.10)		
Total OOP cost (As written)			1.10 (0.08)	0.10 (0.07)
Has Medicaid	**0.09*** **(0.09)**	**-2.46*** **(1.08)**	**0.08*** **(0.09)**	**-2.50*** **(1.08)**
Near poor	1.15 (0.47)	0.14 (0.41)	1.04 (0.42)	0.04 (0.40)
Age	0.95 (0.03)	-0.05 (0.04)	0.96 (0.03)	-0.04 (0.04)
Male	1.10 (0.43)	0.09 (0.39)	1.02 (0.40)	0.02 (0.39)
Nonwhite	1.23 (0.47)	0.21 (0.38)	1.28 (0.49)	0.25 (0.38)
Single	0.85 (0.34)	-0.16 (0.40)	0.89 (0.36)	-0.11 (0.40)
In Medicare Advantage	1.42 (0.54)	0.35 (0.38)	1.72 (0.66)	0.54 (0.38)
Charlson index	1.33 (0.31)	0.28 (0.23)	1.17 (0.26)	0.16 (0.23)
Family Med Clinic	1.15 (0.45)	0.14 (0.40)	1.02 (0.41)	0.02 (0.40)
Constant	9.12 (25.07)	2.21 (2.75)	4.65 (12.78)	1.54 (2.75)
Observations	161	161	161	161
Pseudo R^2	0.106	0.106	0.114	0.114

Standard errors in parentheses
+ $p < 0.10$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Aim 3b: Beneficiaries who experienced CRN will have worse clinical outcomes related to their diabetes than those who did not experience CRN.

See results in Aim (2c), above (Table 11).

Aim 3c: Beneficiaries who experienced CRN will have higher health services utilization than those who did not experience CRN.

See results in Aim (2d), above (Table 12).

Aim 4.

To determine the association between switching plans and differential costs, plan satisfaction, and CRN.

Hypotheses:

Aim 4a: Beneficiaries who switched plans will have lower differential costs (and will have a higher likelihood of being in a lowest-cost plan) than those who did not switch plans.

Differential costs (Table 14): There is no bivariate association between plan switching and differential costs. OLS regression results also indicate that there is no significant association between previous plan switching and differential costs, for both the "generic" and "as written" models. These models are the same as those run in Aim (1c), with the addition of the key [previous plan switch] variable. None of the covariates changed significance from those models and the magnitudes also changed very little.

Table 14: OLS regression results for Aim 4a: The effect of previous switching on differential costs

	"Generic" Coeff	"As written" Coeff
Switched plans	0.02 (0.22)	0.20 (0.26)
Has Medicaid	-0.29 (0.28)	0.60+ (0.35)
Near poor	0.40+ (0.20)	**0.70**** **(0.25)**
Age	0.02 (0.02)	0.00 (0.02)
Male	-0.21 (0.18)	-0.29 (0.23)
Nonwhite	-0.16 (0.18)	-0.29 (0.22)
Single	-0.26 (0.19)	0.19 (0.23)
In Medicare Advantage	-0.32+ (0.19)	**-0.72**** **(0.22)**
Charlson index	0.01 (0.11)	-0.08 (0.13)
Informed choice	0.22 (0.20)	0.25 (0.24)
Insurance agent	-0.08 (0.27)	-0.27 (0.32)
Family Med Clinic	**0.52**** **(0.19)**	0.17 (0.24)
Log med expense (Generic)	-0.00 (0.05)	
Log med expense (As written)		-0.07 (0.08)
Constant	-2.13+ (1.22)	-0.43 (1.49)
Observations	150	156
R^2	0.179	0.222

Standard errors in parentheses
+ $p < 0.10$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Lowest-cost plan enrollment (Table 15): There is no bivariate association between plan switching and lowest-cost plan enrollment. Logistic regression results also indicate that there is no significant association between switching plans and lowest-cost plan enrollment, for "generic" or "as written" models. These models are the same as those run in Aim (1b), with the addition of the key [previous plan switch] variable. All covariates retained significance except for the [insurance agent helped chose plan] variable, which is not significant in this model. This includes the medication expense covariate in both models, with a 139% ("generic")/ 76% ("as written") increase in the odds of being in of a lowest-cost plan for a $1000 increase in medication expense ($p<0.001$). In the "generic" model only, a one-unit increase in the Charlson index comorbitiy score (being sicker) is associated with a 59% decrease in the odds of being in a lowest-cost plan ($p<0.01$) and being one year older is associated with a 10% decrease in the odds of being in a lowest-cost plan ($p<0.05$). In the "as written" model only, being near poor is associated with a 69% decrease in the odds of being in a lowest-cost plan ($p<0.05$).

Table 15: Logistic regression results for Aim 4a: The effect of previous switching on lowest-cost plan enrollment

	"Generic" OR	"Generic" Coeff	"As written" OR	"As written" Coeff
Switched plans	0.93	-0.07	1.08	0.08
	(0.49)	(0.53)	(0.53)	(0.49)
Has Medicaid	1.72	0.54	2.17	0.77
	(1.42)	(0.82)	(1.61)	(0.74)
Near poor	0.67	-0.40	**0.31***	**-1.16***
	(0.37)	(0.55)	**(0.16)**	**(0.51)**
Age	**0.90***	**-0.11***	1.00	-0.00
	(0.04)	**(0.05)**	(0.04)	(0.04)
Male	1.63	0.49	1.74	0.55
	(0.82)	(0.50)	(0.79)	(0.46)
Nonwhite	2.08	0.73	1.14	0.13
	(1.04)	(0.50)	(0.52)	(0.46)
Single	0.89	-0.12	0.59	-0.52
	(0.45)	(0.50)	(0.27)	(0.45)
In Medicare Advantage	1.21	0.19	1.29	0.25
	(0.62)	(0.51)	(0.58)	(0.45)
Charlson index	**0.41***	**-0.88***	1.00	0.00
	(0.14)	**(0.34)**	(0.26)	(0.26)
Informed choice	0.66	-0.42	0.95	-0.05
	(0.35)	(0.54)	(0.47)	(0.50)
Insurance agent	0.32	-1.15	1.34	0.29
	(0.24)	(0.77)	(0.79)	(0.59)
Family Med Clinic	0.35+	-1.04+	1.25	0.22
	(0.21)	(0.58)	(0.57)	(0.46)
Medication expense (Generic)	**2.39*** **	**0.87*** **		
	(0.42)	**(0.17)**		
Medication expense (As written)			**1.76*** **	**0.57*** **
			(0.22)	**(0.13)**
Constant	167.22	5.12	0.05	-2.91
	(603.58)	(3.61)	(0.16)	(3.01)
Observations	160	160	162	162
Pseudo R^2	0.306	0.306	0.195	0.195

Standard errors in parentheses
+ $p < 0.10$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Aim 4b: Beneficiaries who switched plans will have a higher likelihood of being satisfied with their current plan than those who did not switch plans.

There is a significant bivariate association indicating that those who previously switched are also more likely to report dissatisfaction with their current plan ($\chi 2=4.99$; $p<0.05$). There is also a significant multivariate association at the $\alpha=0.10$ level between previous plan switching and current plan satisfaction, with no additional significant covariates in the model. Participants who previously switched plans have 111% higher odds of being dissatisfied with their current plan as compared to participants who did not previously switch plans (OR=2.11; $p<0.10$) (Table 16).

Table 16: Logistic regression results for Aim 4b: The effect of previous switching on plan satisfaction

	OR
Switched plans	2.11+
	(0.94)
Has Medicaid	0.47
	(0.34)
Near poor	1.73
	(0.79)
Age	1.02
	(0.04)
Male	1.12
	(0.48)
Nonwhite	1.04
	(0.44)
Single	1.25
	(0.54)
In Medicare Advantage	0.81
	(0.34)
Charlson index	1.17
	(0.29)
Informed choice	0.50
	(0.23)
Insurance agent	0.76
	(0.43)
Family Med Clinic	1.90
	(0.79)
Medication expense (Generic)	1.11
	(0.12)
Constant	0.03
	(0.08)
Observations	156
Pseudo R^2	0.076

Standard errors in parentheses
+ $p < 0.10$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Aim 4c: Beneficiaries who switched plans will have a lower likelihood of experiencing CRN than those who did not switch plans.

There is no bivariate association between plan switching and CRN. Logistic regression results also indicate that there is no significant association between previous plan switching and the odds of experiencing CRN. Having Medicaid is significantly associated with a 91% decrease in the odds of experiencing CRN relative to participants who do not have Medicaid (OR=0.09; $p<0.05$). There are no additional significant covariates in this model (Table 17).

Table 17: Logistic regression results for Aim 4c: The effect of previous switching on CRN

	OR	Coeff
Switched plans	1.14 (0.51)	0.13 (0.45)
Has Medicaid	**0.09* (0.10)**	**-2.39* (1.10)**
Near poor	1.15 (0.47)	0.14 (0.41)
Age	0.97 (0.04)	-0.03 (0.04)
Male	0.87 (0.35)	-0.14 (0.40)
Nonwhite	1.15 (0.45)	0.14 (0.39)
Single	0.85 (0.34)	-0.16 (0.40)
In Medicare Advantage	1.37 (0.55)	0.32 (0.40)
Charlson index	1.18 (0.28)	0.17 (0.24)
Informed choice	1.03 (0.44)	0.03 (0.42)
Insurance agent	2.50 (1.32)	0.92 (0.53)
Family Med Clinic	1.06 (0.43)	0.05 (0.40)
Medication expense (Generic)	1.08 (0.11)	0.08 (0.10)
Constant	3.23 (8.99)	1.17 (2.78)
Observations	159	159
Pseudo R^2	0.118	0.118

Standard errors in parentheses
* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

CHAPTER 5: DISCUSSION

Implemented under the Medicare Modernization Act of 2003, Medicare Part D provides a federal prescription drug benefit, administered in the private market, for all Medicare beneficiaries. Medicare Part D would work best if patients enrolled in the prescription drug plan that maximizes formulary coverage for their medications and minimizes annual out-of-pocket costs. Failure to enroll into a lowest-cost plan may increase the likelihood of cost-related non-adherence and, ultimately, negatively impact patient outcomes. My dissertation examined the prevalence and effect of being in a lowest-cost plan on critical patient outcomes: CRN; clinical parameters; and health services use among Part D beneficiaries with diabetes. To my knowledge, this is the first prospective cohort study to link patients' plan, CRN and clinical parameters and, as such, represents a contribution to the literature evaluating Medicare Part D.

As in Medicare Part D, enrollees in this study are more likely to be female and minority relative to the general Medicare population.[9] They are also representative of Medicare beneficiaries in general, as 92% of community-dwelling Medicare beneficiaries have at least one chronic condition,[125] and 42% of elderly adults take four or more medications, while 25% take seven or more.[35, 51] This sample of people with diabetics takes an average of 9.2 medications, and over 50% rate their health as fair or poor. They are a fairly chronically-ill population, yet are well-controlled clinically.

Differential costs are substantial (Aim 1)

Aim 1 was a mostly descriptive study to examine the prevalence and predictors of being in a lowest-cost plan. Beneficiaries may be substantially overpaying to obtain their medications. I found that 75% of the sample was enrolled in a prescription drug plan that could result in out-of-pocket costs that are at least 10% higher than the lowest-cost plan for their prescribed medications. When I calculated the difference between their actual costs if they filled all of their medications and the cost of those same medications if they were in a lowest-cost plan, the mean differential cost was $1,215/year (assuming "as written" drugs) or $692/year (assuming generic substitutions). This is a particularly large sum of money in an elderly population, most of whom live on fixed incomes. Given that a large proportion of our sample are poor or near poor, they may have particular difficulty paying

for their medications, despite being enrolled in Medicare Part D. Price sensitivity can affect behavior—even small sums of money can delay seeking needed medical care. It is important to note that there may be reasons why some beneficiaries are choosing to enroll in plans that are not lowest-cost plans, such as personal preference, more generous coverage, brand loyalty, or plan quality.

Based on our results, focusing on differential costs may be more useful than whether or not a person is in a lowest-cost plan. There are several reasons for this. First, differential costs may better reflect the financial burden that affects CRN and, as a continuous variable, has substantially more variation. Second, the dichotomous outcome of being in a lowest-cost plan overlooks the possibility that there is a dollar threshold at which costs become prohibitive enough to impact CRN. For example, a person with differential costs of $6 on a $50 and another person with differential costs of $301 on a $3000 medication expense would both be classified as not being in a plan that is within 10% of a lowest-cost plan. Third, the lowest-cost plan variable assumes that the distribution of plan choices and subsequent probability of enrolling into a lowest-cost plan is identical for all medication expenses. To the extent that this is not true, it introduces omitted variable bias. Given these reasons, the remainder of the discussion, including policy implications, will focus on differential costs.

Differential costs are higher for poorer beneficiaries

The relationship between Medicaid status and differential costs varies between "generic" and "as written" models. In "as written" models, having Medicaid is associated with higher differential costs, whereas in "generic" models, having Medicaid is associated with lower differential costs. This may occur because dual eligibles have access to generous subsidies in the benchmark plans to which they are assigned. However, in most of these plans, coverage of generics is generous and less so of brand-name drugs. Brand coverage is much more restrictive, so "as written" cost estimates may be capturing off-formulary medications that are driving costs significantly higher than those of their non-dual counterparts. Therefore, it is likely that the "generic" cost estimates are a more realistic, conservative assumption of what is happening in the real-world for the *majority* of dually-eligible beneficiaries. Provided that they do not have expensive brand-name medications that their formulary does not cover or that they prefer brand rather than generic (i.e. refuse generic substitution), their costs are generally adequately subsidized. However, there are likely still a *minority* of duals for whom their formulary does not adequately meet their medication needs, and their costs do fall into this situation. Despite an exemptions process to deal with getting off-formulary medications covered, clinicians who deal with this population anecdotally report that this process is rarely used to completion with success.

Those near poor also have higher differential costs ("generic" & "as written"). Unlike the dually-eligible, these beneficiaries were not randomly assigned to plans (and so were not guaranteed as least a basic level of continuity of coverage or baseline level of access). However, like the duals, they are also relatively poor and vulnerable to the consequences of such poverty. That is, they may be more susceptible to the perils of a complex enrollment process such that they may have even fewer resources than the average Medicare beneficiary with which to navigate the enrollment process and system. Indeed, these results indicate that the near poor have significantly higher differential costs relative to the higher income category of participants, which could indicate that they had greater trouble navigating the enrollment process than their higher income counterparts.

Factors that predict CRN (Aim 2)

Three factors were found to be associated with increased CRN. First, as hypothesized, participants with higher differential costs report greater CRN for the "as written," but not "generic," models. This may occur for multiple reasons. It is possible that "as written" differential costs make the overall magnitude of total out-of-pocket costs higher, thus making beneficiaries more susceptible to CRN. It is possible that this relationship actually exists for "as written" and "generic", but the "as written" models allow greater sensitivity in small samples due to larger cost estimates and wider range.

Second, in multiple models (aims 2b&3a), having Medicaid is associated with a decreased reported CRN. This may indicate that dually-eligible beneficiaries are effectively shielded from some of the prohibitive costs that put them at risk for CRN. While costs to the beneficiary are heavily subsidized by CMS, this largely depends upon the beneficiary's medication being on-formulary, which varies by plan. Among qualifying plans, formulary coverage is generally generous for generics and commonly-prescribed medications; however, off-formulary medications are less likely to be covered.

Third, having an agent makes individuals more likely to experience CRN. This finding is interesting because agents' financial incentives may not be aligned with those of beneficiaries, thereby reducing the chance of being enrolled in a lowest-cost plan. The association with CRN suggests that there may be adverse consequences of having agents drive plan choices.

Relationship between CRN and outcomes (Aims 2, 3)

There are an array of factors that may interfere with optimal adherence, including: adequate follow-up, patient perception of treatment benefits, provider-patient relationships, and comorbidities. As such, the ability to detect a relationship between adherence and clinical outcomes may be limited.[87, 126] These results were less able to establish a firm link between CRN and clinical outcomes (HbA1c; BP; lipids). In part, this may be a function of the relatively small sample, especially for lipids. However, this may also be a function of the study participants having relatively good control of these parameters, despite poor self-rated health status. Notably, patients in both clinical venues were recruited from diabetes registries that are used by clinicians to help manage patients' health. Whatever the reason, the good control for these clinical parameters decreases variation in these key outcomes and, as such, decreases our ability to find a statistically significant relationship.

In contrast to the clinical parameters, self-reported health status was significantly associated with CRN in the hypothesized direction, that is, those with higher medication expenses were less likely to report being in good health. It is possible that individuals who report being in poorer health are more likely to skip medications due to cost, rather than that the CRN itself is driving their health status. Either way, this finding further suggests the importance of addressing the barriers that prevent these individuals from obtaining the medications necessary to maintain their health.

As hypothesized, CRN is associated with both higher inpatient and outpatient utilization in the post period. This suggests that individuals who are having trouble paying for medications are also sicker. Indeed, as comorbidities increase, the odds of having an inpatient stays increase by 700%. However, sicker patients have almost 0.8 fewer outpatient visits, which may indicate that they are experiencing barriers to utilizing all health services and may wind up in an inpatient setting.

Plan switching (Aim 4)

Having previously switched plans is not predictive of differential costs, lowest-cost plan enrollment, or CRN. However, those who had previously switched plans were more likely to be dissatisfied with their current plan. In focus groups and surveys, beneficiaries generally indicate that they are satisfied with their current plan.[25, 51, 57] However, beneficiaries also report problems with their plans, despite this satisfaction. These issues may include higher-than-anticipated expense, needing to switch medications due to formulary, or having difficulty obtaining medications.[57] It is possible that this general satisfaction stems from being previously uninsured, or just being unaware that there may be better plan options out there for them. This may indicate that beneficiaries are unaware of less expensive PDP alternatives. Our results suggest people who had a particular reason for switching

plans in the past (i.e costs were too high; they did not like a plan feature or benefit design) may be particularly aware of such similar features in their new plan, and therefore may be more likely to voice dissatisfaction. In contrast, beneficiaries who are unaware of such undesirable plan features may be less likely to report dissatisfaction.

Study limitations

There are several limitations to consider in the design of this study. First, the sample size was relatively small. Despite attempting to contact all eligible patients in both the family medicine and internal medicine clinics, I only had 165 participants who both completed surveys and returned their HIPAA authorization forms. Based on discussions with clinic directors, we expected to enroll between 300 and 400 patients. In our post-hoc power calculations, there is insufficient statistical power to detect a significant effect of a dichotomous key independent variable on a dichotomous outcome variable (aims 2b. & 3b.; 2c. & 3c.—inpatient only; 4b.; 4c.). A sample size of 489 would be required to detect an odds ratio of 1.9. Therefore, where appropriate, all clinical outcome variables in aims (2b) and (3b). (HbA1c, BP, lipids) are used continuously in Aims (2b) and (3b). Therefore, bivariate associations are used as a means of exploratory analysis to detect a potential relationship between CRN and clinical outcomes, with no significant findings.

A related limitation involves the recruitment protocol. We used strategies that were respectful of clinic flow and patient time. Our lower-than-expected sample size may result from several factors. First, 264 people could not be contacted after 6 repeated attempts and one phone message. A majority of these individuals had disconnected phone numbers and/or never answered the phone at all. Practitioners indicate that many of these individuals intentionally give an incorrect phone number to UNC so as to not be contacted. Next, we contacted 285 individuals who were ineligible, most frequently because they did not have Medicare Part D. This percentage may have been high because the area directly surrounding UNC and the patient populations at the Internal Medicine and Family Medicine practices may have a high proportion of retired state employees with the state employees health plan, who opted out of Part D. Although 66 participants who completed surveys did not return HIPAA forms, they were similar to the participants who did return the forms.

There were potential limitations related to operational definitions of several key measures. First, CRN was measured with a widely-used 3-item scale that is dichotomized (adherent or not). In an attempt to increase variation, I scored participants' responses to each question as a 3-point scale and summed across items. This produced a score that ranged from 0 to 5, but the distribution was highly skewed and had little variability. For these reason, I retained the dichotomous variable because

it is consistent with what has been reported in the literature.[86] Using a dichotomous variable decreases variation, so results may have been biased towards null results in Aim 2. Second, income was approximated with a three-level categorical variable: dual (<100% FPL, in addition to asset criteria); near poor (100-250% FPL); and >250% FPL. While we assessed the low-income subsidy using a survey question, telephone interviewers reported that study participants had a difficult time understanding this question. Therefore, it was not used as a covariate in regression analyses. To estimate socioeconomic status, we used WebCIS to identify patients who are eligible for charity care. I count anyone who received charity care in WebCIS (even if it was recently expired) as "near poor." Although individuals may fall in and out of eligibility for this subsidy, it is still a reasonable marker of patients who are socioeconomically vulnerable. Third, data on prescribed medications, clinical parameters, and health care utilization come from WebCIS. Although we will have complete data for these outcomes at UNC, we do not know the extent to which patients may have medications prescribed or utilization outside UNC. We attempted to minimize any potential bias by enrolling only patients who receive primary care from either the family medicine or general internal medicine clinic at UNC.

Fourth, estimates of our cost variables using the PDPF assumes that patients fill all medications as prescribed. To allow flexibility, we considered costs of both filling medications as prescribed ("as written") or allowing generic substitutions. There may also be measurement error in the medication costs variables because these were calculated using the medication list from one point in time (the survey date). Previous research has shown that actual medication use is likely to change over time, with the potential for lowest-cost plan to change with it.[50] While the medication list as of the survey date may not be the same medication list that the beneficiary used from which to choose a plan, these lists will become more similar the closer the date becomes to December 31st, or the date at which the beneficiary assessed plan choice (usually during open enrollment).

Given the way in which costs were estimated, we are not able to differentiate between the components that comprise annual out-of-pocket medication expense. That is, we obtained cost estimates in lowest-cost and actual plans, but do not know the benefit structure of these plans to determine which portion of these costs are deductibles, premiums, or copays. This is a limitation because it introduces heterogeneity into the measure, such that participant decision-making that may be based on these marginal cost components is not captured. We are unaware if a participant purposefully chose a plan to minimize premiums while willing to pay slightly higher copays; the lowest-cost plan measure assumes that they just minimized *total* out-of-pocket costs, without regard for the differentiation between premiums and copays. Our general measure of CRN assumes that it is

the overall cost, not any one component part, that leads to CRN. This may be an erroneous assumption.

Finally, this study sample may have limited generalizability because it was drawn from patients receiving care at one academic medical center. Moreover, their names came from a diabetes registry that is used to increase access to a diabetes disease management program. This may explain why their clinical parameters are under excellent control despite patients reporting being in poor health. In addition, they may have access to more enrollment resources than the general Medicare population when considering programs available in the area, such as those in the School of Pharmacy; in community pharmacies; through local student and community volunteer organizations. Notably, despite these resources, a majority of participants were not in lowest-cost plans, resulting in their having substantially higher out-of-pocket medication costs than necessary.

Policy implications

MedPac considers several performance indicators when monitoring "the ability of the program—under its competitive approach—to meet the Medicare goals of maintaining beneficiary access while holding down program spending."[9] One of these indicators is beneficiaries' access to prescription drugs, and another is the quality of services. Arguably, this research addresses both the access and quality issues by examining the differential costs that are being incurred by beneficiaries to obtain their medications, and whether such excess payments lead to CRN, worse clinical outcomes, or increased health services use.

Implications for Policy and Research

This research informs several policy options to improve Medicare Part D. First, it is important to consider ways to increase the proportion of beneficiaries in lowest-cost plans and/or to decrease differential costs. What might explain the strikingly high proportion of individuals who are not in the lowest-cost plan? Certainly, the complexity of the enrollment process into Medicare Part D and random assignment of patients who are dually eligible for Medicare and Medicaid can contribute to our observation. Several factors may contribute to the low proportion of beneficiaries in lowest-cost plans, including: too much complex information for them to effectively use; infrequent use of the PDPF tool; insufficient access to help resources; lack of plan switching; and the use of agents in plan enrollment.

Above a certain threshold, it is unnecessary for elderly beneficiaries—most of whom live on modest fixed incomes—to overpay for medications that are necessary to manage their chronic conditions and maintain their health. While there may be an acceptable limit at which some beneficiaries choose to pay extra for more generous coverage, the differential costs amounts in the hundreds to thousands of dollars that we found in this research are arguably out of this range and can be addressed through policy interventions.

There are several policy options that CMS should consider. First, it could expand education or outreach efforts to increase the ability of beneficiaries to identify their lowest-cost plan given their prescribed medications. Certainly, that was the intent of the online PDPF tool. However, data from our study and others suggests that even among patients enrolled in primary care, this tool is not widely-used or accessible by this population.[41, 42] Such technical tools are unlikely to be effective because they offer too much information for beneficiaries to digest, and when they become overwhelmed, they choose not to use the tool at all. Alternatively, they are simply unable to access the internet themselves and/or are unaware of the tool's existence.

Second, CMS could develop less technical tools to direct patients into lowest-cost plans. However, simple educational interventions are not likely to work. Non-web-based strategies will be less scalable to large segments of the population. And, interventions that require health care personnel (e.g., physicians, nurses, pharmacists) may be impractical and expensive unless specific incentives are provided.

Third, enrollment processes and/or plan choices could be simplified. While this would be a shift away from the fundamental premise upon which Medicare Part D was built, it may make sense when considering the chronically-ill, elderly population which the benefit is intended to serve. A recent survey indicated that 66% of people favored decreasing the number of plan options and 84% of people favored obtaining coverage directly from Medicare.[52] There were few significant demographic characteristics to predict which types of people support these two policy options, [52] which may indicate that the support is widespread.

Fourth, CMS could provide financial incentives to patients for enrolling in lowest-cost plans. For example, they could provide a rebate or discount to patients who, at the annual enrollment, use the PDPF to make their decisions. Given the relationship between CRN and utilization, such a strategy may well pay short- and long-term dividends to CMS. Alternatively, given differences between "as written" and "generic" cost estimates, CMS could provide incentives to patients and/or providers to implement generic substitution unless clinically contraindicated. Substituting generic for brand-name medications will reduce differential costs and has the potential to also reduce CRN.

There is very little cost (both time and monetary) to implementing such policies in clinical practice, and at UNC and elsewhere, this practice is already widespread. Many Part D plans have already successfully steered beneficiaries from brand-name drugs to their generic equivalents since the benefit began.[9] However, it is not clear that the shift towards generic use is due to the implementation of Part D itself. Rather, one study showed that there was already a time trend towards more generics use, both among Part D and non-Part D enrollees, and the growth rate of generic use was lower among Part D enrollees, with results varying by drug class.[127] In either case, the results of this research suggest that the increased use of generics relative to brand-name drugs can have a beneficial impact on patient outcomes and the practice should both continue and be expanded.

It is also important to consider whether beneficiary-centered assignment may be a more efficient policy with which to enroll duals. Costs are effectively minimized for duals, if they were randomly-assigned/chose/switched into to a plan with a formulary that sufficiently covers their medications. This may be happening for some duals, but not others, with much of this depending upon the combination of plan assignment and formulary coverage (given that costs are standardized). In this sense, Medicaid may be protective against CRN for the majority of duals who end up among the subset of benchmark plans with generous formulary coverage of generics. Beneficiary-centered assignment would take into account whether it can do a better job of matching beneficiaries with a plan that most closely fits their medication needs, or whether the costs (financial, time) associated with it are worth the investment, given the relatively standardized costs and formularies among benchmark plans.

Lastly, CMS should consider the structure of Part D in the context of health care reform. Under health reform, insurance is partly provided through Health Benefit Exchanges. The structure of these Exchanges bears similarities to the way in which Part D is delivered: the federal government contracts with private insurers; there are minimum standards that plans must meet; and competition and choice are hallmarks of the program. These similarities are such that the complexities associated with Part D enrollment have the potential to extend into the new insurance marketplace.

Some of the limitations of this study could be addressed in future research. This could include replicating these findings with a larger dataset that follows participants over a longer study period. CMS Part D data could be used to examine out-of-pocket spending and a different set of outcomes, linked to Parts A & B data. Individual plans would not be identifiable, and claims data would be used rather that medical record data. This would offer additional strengths in terms of having actual prescription fill data, but would lose the ability to detect clinical parameters as outcomes.

Alternatively, the results of this study could inform future research that explores the reasons *why* individuals are not in lowest-cost plans; such research could include qualitative methods to further explore enrollment decisions and processes. A comparative study could also prospectively follow individuals who have received enrollment assistance (i.e. SeniorPharmassist) versus those who have not (such as participants in this study) and track their outcomes for longer periods of time.

Conclusion

This research represents a contribution to the literature by being among the first studies to examine enrollment decisions, costs, CRN, and clinical parameters in an elderly Part D cohort. It also confirms the findings of several other recent studies reporting that only a minority of beneficiaries are enrolled in lowest-cost plans.[37, 38, 56] The results of this study should be of interest to clinicians and policymakers. It is important to understand the impact of health policies on the beneficiaries that they are intended to serve, particularly in the case of elderly beneficiaries who are vulnerable to the consequences of a benefit that can be complicated to navigate. This research has demonstrated that policy implementation can impact patient costs and outcomes, and this lesson will be important to carry forward in the context of health reform.

APPENDIX A: Telephone survey

Hi, my name is _____ and I am calling from UNC to request your help with a research study that we are conducting. You should have received a letter from UNC within the last 2 weeks. The letter included a $5 gift card. Do you remember receiving this letter? As you probably know, Medicare Part D began to cover prescription drugs in 2006. I am trying to learn about Part D by talking to up to 400 Medicare beneficiaries about the prescription drug benefit, and I could use your help to learn more.

If you are willing to help me, I would like to ask you a few questions over the phone that should take no longer than 5 minutes, and I may call again only if I need you to clarify an answer. There are no costs to participate. Your participation is completely voluntary and your answers will be kept confidential. You can skip or refuse to answer any of the questions that I ask you and can stop taking the survey at any time. The only foreseeable risk might be if your identity were revealed, but I will not record your name with your responses, so this cannot happen. Although your participation will not benefit you personally, you will help us to gain important knowledge about Medicare Part D. Are you willing to participate by answering this short survey?

1. Do you have Medicare Part D to help you pay for your medications?	___ Yes ___ No ___ Refused ___ Don't know
2. How satisfied are you with your current Medicare prescription drug plan?	___ Very satisfied ___ Somewhat satisfied ___ Neutral ___ Somewhat dissatisfied ___ Very dissatisfied ___ Don't know
3. In the past year, have you ever switched Medicare Part D plans? b. (If yes), in which month did you switch plans? c. (If yes), what was the reason that you switched?	___ Yes ___ No ___ Refused ___ Don't know
4. When you first enrolled into Medicare Part D, how did you choose a plan?	

5. Did you have help choosing a plan (for example, from an agent, physician, pharmacist, family member, friend, or other caregiver?) b. (If yes), from whom did you receive help?	___ Yes ___ No ___ Refused ___ Don't know
6. Do you receive extra help paying for your medications through the Medicare Prescription Drug Plan? This means that you receive help paying for some or all of your monthly premium, and, in some cases, help paying for other medication costs. This was also referred to as the Low-Income Subsidy Program offered through Medicare and the Social Security Administration.	___ Yes ___ No ___ Refused ___ Don't know
Now I would like to ask you a few questions about your medications. 7. During this year (current year), were any medications prescribed for you that you did not get because you thought it would cost too much? Please include refills of earlier prescriptions as well as prescriptions that were written or phoned in by a doctor.	___ Yes ___ No ___ Refused ___ Don't know
8. Please tell me how often during this year (current year) you have done any of the following things, responding "often, sometimes, or never" a. Taken smaller doses of a medicine to make the medicine last longer? b. Skipped doses to make the medicine last longer? c. Asked for generics instead of brand name drugs?	___ Often ___ Sometimes ___ Never ___ Refused ___ Don't know ___ Often ___ Sometimes ___ Never ___ Refused ___ Don't know ___ Often ___ Sometimes ___ Never ___ Refused ___ Don't know

9. In general, would you say your health is:	___ Excellent ___ Very Good ___ Good ___ Fair ___ Poor
10. In general, do you usually get vaccines and immunizations such as the flu shot or pneumonia vaccine?	___ Yes ___ No ___ Refused ___ Don't know
11. What is the name of your Medicare Part D plan? [Which company provides your insurance? If you are unsure, I can help you to figure this out by looking at your Medicare card while we are on the phone together…]	

Thank you so much for your time. Another part of this project involves getting information from your medical record about your health and medications. This information would help us understand how Medicare Part D might best help beneficiaries such as you. Any information about you will be kept confidential and will not be identifiable. Would it be okay with you if I had access to your medical record?

(Y)

Ok, thank you. In order for me to be allowed to look at your medical chart, I will need you to sign a permission form. I mailed this permission form in with the letter that I sent you last week. Do you recall getting this form? It is 2 pages long and 2 copies of it were mailed to you.

Can you please sign one of the copies of this form and mail it back to me in the envelope that was included? There is already a stamp on it so all that you will need to do it sign it and put it in the mail.

Thanks again for your time. I really appreciate your help today. If you have any further questions, you can contact me at 919-966-6446.

APPENDIX B: General Internal Medicine recruitment letter

INTERNAL MEDICINE CLINIC

You are getting this letter because you have received care in the Internal Medicine Clinic at the Ambulatory Care Center at UNC-Chapel Hill. Currently, we are conducting a research study entitled "Plan enrollment and costs for Medicare Part D beneficiaries," to better understand Medicare's prescription drug benefit ("Medicare Part D"). To do this, we are requesting your help. We need to ask people like you about your experiences with the Medicare drug benefit. What we learn in the study could eventually help to improve the program.

In the coming weeks, you will be receiving a phone call to ask you about your experiences with Medicare Part D. If you do not wish to receive a phone call, you may call 1-800-243-0887 to alert us that you do not want to be contacted.

If you choose to participate in this study, we will ask you about your experiences with Part D during a phone conversation that should last no more than 5 minutes. Choosing not to participate in this study will not affect the care that you receive at UNC.

We have included a $5 gift card with this letter as a small token of our appreciation for helping with this study. You may keep this gift card whether or not you choose to participate in the study.

The attached form, titled "*HIPAA Authorization for Use and Disclosure of Health Information for Research Purposes*," grants permission for us to access your health care record. If you are willing to be in the study, you should sign one copy of this form and keep the other copy for your records. You can use the enclosed, stamped envelope to send this form back to the researchers at UNC. Once you send us this form, we will be able to access your health care record only to get study information. In our study, none of this information will be connected to your name.

If you have any additional questions, you can contact Kristin Geonnotti at 919-966-6446.

Thank you for your consideration.

Sincerely,

Thomas M. Miller, MD
Director, Internal Medicine Clinic

Internal Medicine Clinic at the Ambulatory Care Center
Mason Farm Rd. & S. Columbia St., CB # 7705, Chapel Hill, NC 27514
Telephone 919-966-1459 ● Fax 919-843-9355

APPENDIX C: Family Medicine Center recruitment letter

You are getting this letter because you have received care in the Family Medicine Center at UNC-Chapel Hill. Currently, we are conducting a research study entitled "Plan enrollment and costs for Medicare Part D beneficiaries," to better understand Medicare's prescription drug benefit ("Medicare Part D"). To do this, we are requesting your help. We need to ask people like you about your experiences with the Medicare drug benefit. What we learn in the study could eventually help to improve the program.

In the coming weeks, you will be receiving a phone call to ask you about your experiences with Medicare Part D. If you do not wish to receive a phone call, you may call 1-800-243-0887 to alert us that you do not want to be contacted.

If you choose to participate in this study, we will ask you about your experiences with Part D during a phone conversation that should last no more than 5 minutes. Choosing not to participate in this study will not affect the care that you receive at UNC.

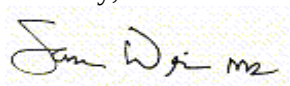
We have included a $5 gift card with this letter as a small token of our appreciation for helping with this study. You may keep this gift card whether or not you choose to participate in the study.

The attached form, titled "*HIPAA Authorization for Use and Disclosure of Health Information for Research Purposes*," grants permission for us to access your health care record. If you are willing to be in the study, you should sign one copy of this form and keep the other copy for your records. You can use the enclosed, stamped envelope to send this form back to the researchers at UNC. Once you send us this form, we will be able to access your health care record only to get study information. In our study, none of this information will be connected to your name.

If you have any additional questions, you can contact Kristin Geonnotti at 919-966-6446.

Thank you for your consideration.

Sincerely,



Samuel Weir, MD
Director,
Family Medicine Center

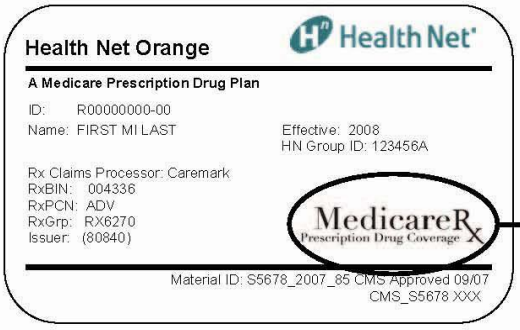
The University of North Carolina at Chapel Hill Family Medicine Center, William B. Aycock Family Medicine Building, CB# 7586 Manning Drive, Chapel Hill, NC 27599-7586 • Telephone: (919) 966-0210 • Fax: (919) 966-6126
www.fammed.unc.edu/fpc/fpc.htm

Samuel Weir, MD	**Susan Slatkoff, MD**	**Thomas Koonce, MD**	**Susan Baize**
FMC Director	**FMC Associate Director**	**FMC Associate Director**	**Practice Manager**
Sam_Weir@med.unc.edu	**Susan_Slatkoff@med.unc.edu**	**Thomas_Koonce@med.unc.edu**	**Phone: (919) 966-1596**
			sbaize@unch.unc.edu

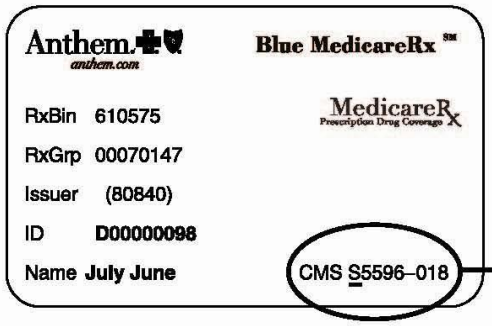
APPENDIX D: Enclosure to facilitate Part D plan identification

Sample Cards for Medicare Prescription Drug Coverage

These are some sample cards to give you an idea of what your Medicare Part D card looks like. The company name will be different depending on which company provides your drug insurance. During the phone interview, we may ask you to get your card so that we can properly identify which Part D plan you have.



Your card will have this MedicareRx logo.



Your card will have an ID number like this. It can start with 'S' or 'H'

Your ID number could also look like this. This number starts with 'H'

APPENDIX E: HIPAA consent form

University of North Carolina-Chapel Hill
HIPAA Authorization for Use and Disclosure of Health Information for Research Purposes

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IRB Study # 08-1156

Title of Study: Plan enrollment and costs for Medicare Part D beneficiaries

Principal Investigator: Kristin Geonnotti
Mailing Address for UNC-Chapel Hill Department:
Cecil G. Sheps Center for Health Services Research
The University of North Carolina at Chapel Hill
725 Martin Luther King Jr. Blvd.
CB# 7590
Chapel Hill, NC 27599

This is a permission called a "HIPAA authorization." It is required by the "Health Insurance Portability and Accountability Act of 1996" (known as "HIPAA") in order for us to get information from your medical records or health insurance records to use in this research study.

---

1. If you sign this HIPAA authorization form, you are giving your permission for the following people or groups to give the researchers certain information (described in #2 below) about you:

Any health care providers or health care professionals that have provided health services or treatment for you such as physicians, clinics, hospitals, pharmacies, diagnostics centers, laboratories, treatment or surgical centers, including the UNC Health Care System.

2. If you sign this HIPAA authorization form, this is the health information about you that the people or groups listed in #1 may give to the researchers to use in this research study:

Information about your medical visits; lab values; prescription drug plan; and your treatment (including conditions and medications prescribed for you)

3. The HIPAA protections that apply to your medical records will not apply to your information when it is in the research study records. Your information in the research study records may also be shared with, used by or seen by the sponsor of the research study, the sponsor's representatives, officials of the IRB, and certain employees of the university or government agencies if needed to oversee the research study. HIPAA rules do not usually apply to those persons. There are multiple ways that the researchers will protect your confidentiality. The study dataset will not contain any individual identifiers, meaning that your information will not be linked to your name in any way. All data will be protected using password protection and locked files. The data will be destroyed when the study is over. You can ask the researchers any questions about what they will do with your personal information and how they will protect your personal information in this research study.

4. If this research study creates medical information about you that will go into your medical record, you may not be able to see the research study information in your medical record until the entire research study is over.

5. If you want to participate in this research study, you must sign this HIPAA authorization form to allow the people or groups listed in #1on this form to give access to the information about you that is listed in #2 on this form. If you do not want to sign this HIPAA authorization form, you cannot participate in this research study. However, not signing the authorization form will not change your right to treatment, payment, enrollment or eligibility for medical services outside of this research study.

6. This HIPAA authorization will stop when the study is over.

7. You have the right to stop this HIPAA authorization at any time. HIPAA rules are that if you want to stop this HIPAA authorization, you must do that in writing. You may give your written stop of this HIPAA authorization directly to Principal Investigator or researcher or you may mail it to the department mailing address listed at the top of this form, or you may give it to one of the researchers in this study and tell the researcher to send it to any person or group the researcher has given a copy of this HIPAA authorization. Stopping this HIPAA authorization will not stop information sharing that has already happened.

8. You will be given a copy of this signed HIPAA authorization.

_____ _____

Signature of Research Subject Date

_____

Print Name of Research Subject

APPENDIX F: Decision rules for entering medications into the PDPF tool

1. **PRN medications:** All medications prescribed on an "as needed" basis will be entered as 1 fill/year. This includes nitroglycerin, which technically should be filled 2/year (medication should be refilled every 6 months due to expiration), but for consistency all PRN meds will be entered this way. This will lead to more conservative cost estimates.

2. **Insulin**: Always choose the basic insulin option, unless WebCIS prescription specifically states that something else is prescribed (pen, mix, etc)
    - Humalog pens come as 5 x 3ml pens/box
    - Lantus: 10 mL vials; 3 mL cartridge system—package of 5; 3 mL SoloStar—package of 5

3. **Inhalers**: Albuterol inhalers are not available generically, and thus only albuterol sulfate tabs and nebulizer are in PDPF. Proventil HFA is entered instead when albuterol sulfate inhaler is prescribed.
    - Often times inhalers are prescribed PRN, but not always. For those prescribed PRN, follow decision rule #1 and enter as 1 fill per year. For those written to be refilled more often, enter into PDPF as prescribed. Clinicians may prescribe them both ways depending upon condition and desired use.
    - Nebulizers are covered by Part B, unless the person does not have Part B and only has Part D (this is very rare). Therefore, exclude nebulizers from being put into the PDPF because Part B will cover them for everyone in this sample.
    - 90 mcg = 1 puff. 200 inhalations/canister (Albuterol)

4. **Standard inhaler doses**:
    - Combivent: 2 inhalations x 4 times a day. 14.7g inhaler = 200 puffs
    - Flovent: 440 mcg x twice/day. 120 puffs/1 box
    - Atrovent: 200 puff/inhaler
    - Advair: choose the 60/pack option. This corresponds with standard dose (1 inhalation x twice/day)
    - Spiriva: each capsule = 18 mcg; standard dose = 1 capsule once daily; 3 cartons available (5 capsules; 30 capsules; 90 capsules)

5. **Eye drops**: Always chose the 10 ml bottle option (1/month), as this one is most-commonly used. (Further information not specified in WebCIS).

6. **Oxygen**: Covered by Part B, so exclude from PDPF.

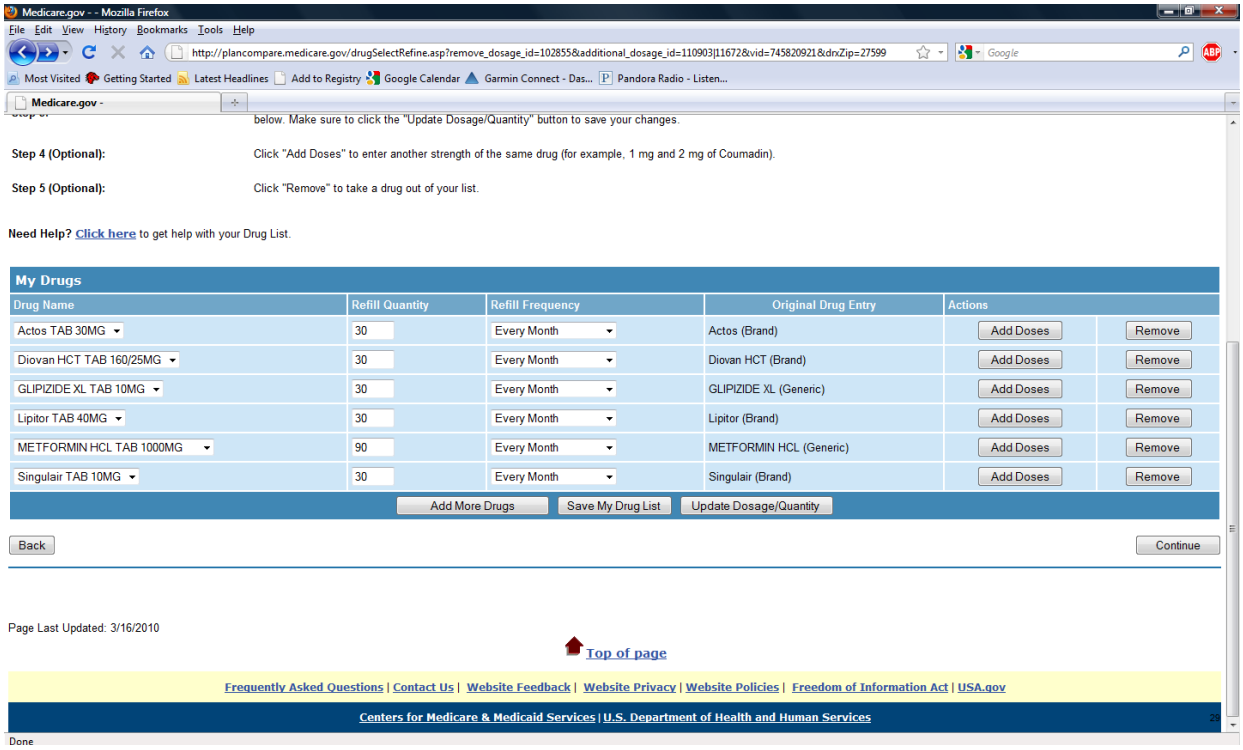
7. **Phenergan:** When phenergan is prescribed, enter "promethazine" into PDPF. This is the generic name and usually what is dispensed when the tablet form is needed.

8. **Proscar**: Enter Proscar as Finasteride. Proscar went off patent in 2009 and is not an available option in the PDPF. Again, this errs on the side of a more conservative cost estimate.

9. **Potassium Chloride:** This is covered by Part D (under the category "electrolyte/replenisher"). In PDPF, scroll down to choose the right dosage.

10. **Antibiotics:** Exclude short-term antibiotics. But there are some instances in which an antibiotic may be prescribed long-term. Determine based on Qty RXD and Refills and put into PDPF accordingly.

APPENDIX G: Prescription Drug Plan Finder example



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